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## The Smart Heart Self-Care First Pilot Program

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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

Samantha Mancuso, Student

Dr. Melanie Hardin-Pierce, Advisor

Running head: SMART HEART PILOT PROGRAM

Final DNP Project Report  
The Smart Heart Self-Care First Pilot Program

Samantha Mancuso, BSN, RN

University of Kentucky  
College of Nursing  
Fall 2016

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### Acknowledgements

Without the support of my committee, I would not have been able to successfully complete the aims of this pilot program. I would like to personally thank Dr. Melanie Hardin-Pierce, Dr. Chizimuzo Okoli, and Dr. Lacey Buckler for their guidance, scholarship support, and encouragement throughout this process. More specifically, some faculty important in the planning phase includes Dr. Diana Inman and Dr. Warshawsky in addition to Dr. Patricia Howard who helped with the research aspects of this project. Whitney Kurtz-Ogilvie has been instrumental in helping me to become a better writer and communicate my ideas in a scholarly manner.

For the planning and design phase of this project, I would like to thank first and foremost Andrew Harover who designed the automated website for text message delivery. Also, Jason Curriden is a health literacy specialist who helped me develop the text messages and ensure a low health literacy reading level for the information provided to each participant. Other honorable mentions in the dissemination of incentives for participation include Judi Dunn who is the patient education manager of the Don and Cathy Jacobs Health Education Library as well as Abby Thorne who is the medical librarian who works with Judi. In addition, information collected from Andrew Carr at the finance department was obtained to determine sample characteristics crucial to the design of this pilot.

Finally, I would like to thank Krista Lewis (Cardiac Discharge Planner) and Candice Falls (Heart Failure Nurse Practitioner) for helping me recruit participants to join the pilot study. Without them, this pilot would not have been successful.

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### Abstract

**Purpose:** The Smart Heart Self-Care First Pilot Program (SHSCF) offers a transitional care intervention focusing on the self-care of hospitalized heart failure patients who are discharged home. It utilizes assessment, communication and education components to encourage behavior modification (improved self-care) through telehealth methodology.

**Background and Significance:** Heart failure related admissions, as a primary or secondary diagnosis, are among the leading causes of hospitalizations in the United States (Emory Healthcare, 2016). Surprisingly, of those patients discharged with a primary diagnosis of heart failure, 20% are readmitted to the hospital within thirty days (Feltner et. al, 2014). Heart failure related re-hospitalizations highlight a growing need for transitional care from the inpatient setting to the home. Thus, heart failure self-management programs focusing on self-care skills and education are becoming increasingly popular among institutions (Baker et al., 2011).

**Procedures:** Twenty participants were enrolled into this randomized controlled trial. Twelve patients received the usual or standard of care based on Heart Failure Core Measures and the other 8 participants received the text messaging intervention. Assessment of self-care, depression symptoms and anxiety symptoms was obtained at baseline and at the 30-day follow-up time frame. For those patients in the intervention group, the delivery of text messages was daily for thirty days after discharge. Additional outcomes evaluated post intervention included hospital readmissions and quality of life.

**Results:** The sample was primarily male (70%), Caucasian (85%), urban (60%), mostly middle aged (mean age= 49.1, SD= 14.9) and not currently married (60%). On average, participants had mild depression and anxiety symptoms (mean PHQ-9=7.2, SD=5.1; mean GAD-7=5.3, SD=5.6) of which 25% of the intervention and 33.3% of the control group had moderate to severe depression symptom scores. There were no significant differences in self-care, depression symptoms, or anxiety symptoms between the control and intervention groups pre and post intervention. There was a readmission rate of 25% in both the intervention and control groups.

**Implications for Nursing Practice:** Self-management programs offer hope to providers and patients as they transition from an acute care facility to home. Specifically, telehealth methods show promise in increasing provider and patient communication as well as access to specialty care. This program highlights how the routine screening for depression and anxiety symptoms in addition to education could be beneficial in the HF population, encompassing a holistic approach to care through the evaluation of emotional and not just physical health.



### The Smart Heart Self-Care First Pilot Program

Patient engagement can be influenced by a patient's confidence, motivation, and determination to be active in their care (James, 2013). Patient activation as referred to by James (2013), explains that those patients who are willing to develop the skills needed to care for themselves as well as modify their behavior may have better outcomes compared to those patients who lack activation. In the context of heart failure (HF), patient engagement is essential to the prevention of hospitalization, early mortality, and advancing disease. The physical symptoms experienced by patients with HF may contribute to psychological well-being, indicating an overlap between emotional and physical health. This overlap may account for the ability to care for oneself, called self-care, and may help to predict those patients at greater risk for poor clinical and psychological outcomes. The Smart Heart Self-Care First (SHSCF) Pilot Program was designed with this concept in mind. The planning, implementation, and evaluation process of this pilot study will be outlined.

### **Background & Significance**

Approximately 5.8 million people in the United States have heart failure (HF), an estimate projected to increase by 3 million by the year 2030 (Feltner et. al, 2014). Within this population, approximately 50% of people will die within 5 years of being diagnosed, contributing to an alarming mortality rate (Centers for Disease Control and Prevention, 2016). In 2011, 58,309 deaths were attributed to HF, accounting for 1 in 9 causes of death in the United States, signifying the value of research on interventions to improve HF outcomes (CDC, 2016).

In addition to escalating mortality rates, an annual cost of \$30.7 billion related to HF in lost productivity, health care services, and medications plagues the United States (CDC, 2016). Approximately 11 million provider visits each year are attributed to HF and it is the leading

diagnosis in 875,000 hospitalizations in patients greater than 65 years of age (Emory Healthcare, 2016). HF-related admissions, as a primary or secondary diagnosis, are among the leading cause of hospitalizations in the United States which is approximately 20% (Emory Healthcare, 2016). Surprisingly, of those patients discharged with a primary diagnosis of HF, 20% are readmitted to the hospital within thirty days (Feltner et al, 2014). A reduction or absence of reimbursement for care as an implication of the Affordable Care Act has gained the attention of institutions nationwide to address this problem of HF-related 30 day re-admissions (Feltner et al, 2014).

There are several factors that affect HF outcomes, especially psychological co-morbidities. Mood disorders, such as anxiety and depression, are psychological conditions that may impair physical and emotional functional status. It has been suggested that depression specifically, may result in poorer HF outcomes such as increased mortality, more frequent hospitalizations, and decreased functional status (Polikandrioti et al., 2015). According to Polikandrioti et al. (2015), the failure to recognize symptoms of depression and anxiety may account for the alarmingly high mortality rate the HF population still faces. It has been suggested that these symptoms are frequently missed by healthcare providers and not adequately treated which could have major implications on adherence to treatment regimens (Polikandrioti et al., 2015). Therefore, the recommendation set forth by the American Heart Association (AHA) in 2009 to routinely screen for depression in patients with HF is likely to capture those patients at risk for poor self-care and intervene early.

This highlights a growing need for transitional care from the inpatient setting to the home within each community. Disease management programs focusing on self-care interventions and education are becoming increasingly popular among institutions (Baker et al., 2011). Self-care can be defined as those behaviors incorporated into a person's daily routine that optimize HF

therapies including daily weights, salt restriction, daily exercise, medication adherence, smoking cessation, and maintaining a well-balanced diet (Lee et al., 2015). Providers expect that assessment and targeted multifaceted interventions promoting HF self-care will improve self-care behaviors, decrease HF specific readmissions to the hospital, improve patient outcomes and disease management, improve quality of life, and reduce annual costs.

### **Biopsychosocial Holistic Model of Cardiovascular Health**

In the biopsychosocial holistic model, the biological, psychological, and social realms of health interact with one another (Thomas et al., 2008). An imbalance or disruption of any of the domains can lead to increased disease severity (of any kind) and acute decline (Lloyd-Jones et al., 2010; Thomas et al., 2008). This model can be applied to any chronic disease process but is especially useful in explaining why patients with HF may need psychological intervention and social support in addition to medical management to slow the progression of HF.

Specifically, depression and anxiety, psychological realms of health, interact with biological processes in HF by decreasing neuro-hormonal regulation (Holsboer & Ising, 2008; Cameron, Abelson, & Young, 2004), disruption of the autonomic nervous system (Licht, de Geus, Zitman et al., 2008; Licht, de Geus, van Dyck et al., 2009), and promotion of inflammatory pathways through cytokine and platelet activation (Morel-Kopp et al., 2009; Leo et al., 2006; Zafar et al., 2010). Depression and anxiety share similar pathophysiological pathways with HF, suggesting that their co-morbidities may have an amplified detrimental effect on HF.

### **Objectives**

The Smart Heart Self-Care First Program (SHSCF) offers a transitional care intervention focusing on the self-care of hospitalized HF patients who are discharged home. It utilizes assessment, communication, and education components as its foundation to encourage an

overarching goal of behavior modification (improved self-care). The goal of this program is to facilitate improved self-care through telehealth interventions, provide increased communication with patients after discharge and throughout the transitional period. The purpose of the evaluation project is to assess the implementation of the telehealth intervention and make changes so that the objectives of the intervention can be met. The specific aims of this program are:

- Assess HF self-care for each participant utilizing the Self-Care Heart Failure Index Tool (SCHFI).
- Reinforce HF self-care education after discharge through telehealth interventions (daily text messaging)
- Improve and increase communication with HF patients after discharge through telehealth interventions.
- Improve HF self-care scores after the intervention.
- Prevent readmission to the hospital within 30 days of discharge.

### **Study Design**

This study was based on a randomized control trial of 20 participants from a cohort of hospitalized HF patients at the University of Kentucky (UK) Chandler Medical Center.

Participants were selected for randomization based on a pre-determined ordering (See Table 1).

Although the initial target was 30 participants, due to time-constraints, only 20 were recruited.

The control group for this study (Group 1) received usual care and were administered SCHFI at discharge and then again thirty days after discharge. The usual care was derived from HF Core Measures Education Packet which includes assistance from a discharge planner for the coordination of home health services, ensuring access to medications, establishing a follow-up

appointment within one to two weeks of discharge, and HF education based on Core Measures provided by the staff nurse.

The intervention group (Group 2) were also given the HF Core Measure Education packet and administered the SCHFI prior to discharge and at 30 days after the telehealth intervention. In addition to the HF Core Measure Education, HF self-care text messages were sent from a website in which a patient phone number can be added as the only identifying information. This concept of using a website for text delivery has been used before in a study evaluating self-care in the African American HF population (Nundy et al., 2013). From the website, each participant received pre-programmed text messages at the same time of day each day for 30 days (See Appendix J for the list of automated pre-programmed text messages on HF self-care along with the patient and message list). For each participant (identified as a 4-digit ID code), the time that the message was delivered (and that it was delivered successfully) was logged to ensure the proper dose of the intervention was delivered. The website kept a log of how many participants were “active” at any given time which means that the participant was currently getting the text messages and how many messages had been received/sent. It also showed which participants had received all the scheduled text messages; these participants were designated as “finished” vs. patients who were still receiving the intervention who were designated as “active.”

A 30-day trial was performed to verify that the website worked consistently, ensuring the delivery of each text message in the correct sequence by the principal investigator. When a patient was enrolled, they were sent a “test message” to ensure that the text messaging system was working appropriately as well as to confirm the number from which the messages were delivered. This was not achievable in some scenarios if the patient’s cell phone was not charged

(on) or if the patient did not have their phone in the hospital because it was shared with a significant other. For those participants, the number used by Twilio was written down and given to the participant to verify once they got home that they had received the test message. Test messages were entered and verified on the website (See Figure 1). Random letters were used for the name and no start date was entered to send the phone number verification test message. When the test message was ready to be sent the “send a test msg” turned from yellow to green. A check mark would appear next to that box to confirm delivery once the message was sent.

### **Outcome Measures**

The primary outcomes of this study are changes in self-care score, and anxiety and depression symptom scales. Long term outcomes of the study include quality of life (measured after the study in both control and intervention group; post -test only design), depressive symptoms, and anxious symptoms 1 month after the intervention as well as 30 day readmissions (see Table 2).

### **Self-Care**

Self-care was measured by the SCHFI, which has been studied extensively for its validity and reliability. SCHFI evaluates self-care maintenance, self-care management, and self-care confidence levels. It also has 6 aspects of validity compared to the European Heart Failure Self-Care Behavioral Scale 9 (EHFScBS-9) which has 5 aspects. SCHFI shows changes in self-care over time more than the EHFScBS-9 (Cameron, Worrall-Carter, Driscoll, & Stewart, 2009; Jaarsma et. al., 2013; Lee et. al., 2013; Riegel & Dickson, 2008). For this reason, SCHFI was chosen as the tool of choice to determine if the telehealth intervention in this study affected self-care pre and post intervention. Another reason why SCHFI was elected as the tool to determine self-care for this study was because it identifies the two symptoms (trouble breathing and ankle

swelling) most prevalent in patients with a heart failure exacerbation.

### **Depression Symptoms**

Depressive symptoms were assessed with the Personal Health Questionnaire (PHQ-9; see Appendix C). The PHQ-9 demonstrates evidence of reliability and validity in various other populations of hospitalized patients and in the outpatient setting (Hammash, Hall, Lennie, Heo, Chung, Suk Lee, & Moser, 2013). The PHQ-9 has not been validated in heart failure patients but was chosen for its brevity and usability in assessing depressive symptoms compared to the Beck Depression Inventory II (BDI-II) that is much longer and requires more time to complete. Recently, in a study comparing the depressive symptoms of patients using the PHQ-9 and the Beck Depression Inventory showed that the PHQ-9 was a valid measure of depressive symptomology in HF patients (Hammash et al., 2013). This has important implications if the results are minimally clinically significant because the assessment of depressive symptoms should be assessed readily and promptly prior to discharge in an acute care setting.

### **Anxiety Symptoms**

Anxiety symptoms were assessed using the Generalized Anxiety Disorder-7 Scale (GAD-7; see Appendix D). Although the measurement of anxiety in heart failure patients has not yet been standardized, the GAD-7 was chosen for its ability to assess anxiety severity in the last two weeks (Kroenke, Spitzer, Williams, & Lowe, 2010). The GAD-7 has correlation with other well established scales in heart failure patients such as the Beck Depression Inventory anxiety subscale ( $r=0.72$ ) and demonstrates validity and internal consistency among primary care patients (Kroenke et al., 2010).

**Quality of Life**

Quality of life was assessed with the Minnesota Living with Heart Failure Questionnaire-21 (MLWHFQ-21; see Appendix E). It measures physical (8 questions) and emotional (5 questions) quality of life with a total of 21 items. The scale is scored from 0-105 with 0 indicating the best quality of life and increasing scores indicate poorer quality of life (Garin, et al., 2014). The MLWHFQ-21, which has been extensively tested for reliability and validity, has also been used in 21 different countries, confirming it is the most widely used tool for health-related quality of life (Garin et al., 2014).

**Readmission Rates**

Readmission rates within 30 days of discharge to an inpatient facility was examined as the proportion of participants within the intervention and control group that were readmitted within the 30-day intervention time-point. The electronic medical record was used to retrieve this information as well as calling each participant to verify if they have been readmitted to the hospital. For participants of the study who are admitted at other hospitals, this information will be retrieved by phone call.

**Study Population**

The University of Kentucky (UK) has an adequate amount of heart failure patients to include approximately 20 total patients (8 in the intervention group and 12 in the control group) over the course of 2 months into the pilot program. Data collected by the UK finance department including UK Healthcare HF Inpatient Demographics (A. Carr, personal communication, August 3, 2015) was used to determine the sample for this intervention which was initially projected to be 50. The sample mostly comprised patients from the Fayette, Madison, Clark, Jessamine, Laurel, Franklin, and Scott Counties in Kentucky. The HF



population at UK has increased exponentially in recent years, serving approximately 3,449 inpatient visits in 2014 compared to 4,005 patients just from January until June of 2015. The major payer sources identified for the HF population served include 64% Medicare, 20.9% Medicaid, 10.1% Managed Care, and 5% self-pay or governmental insurance from January to June of 2015 (Table 3).

Data collected as of August 2015, showed that the majority of inpatient discharges occur in patients older than 45 years (Table 4). There are approximately 50-60 discharges each month with a primary diagnosis of HF, a number that reflects increasing admissions over the last few years and an adequate population to sample from for this pilot study (A. Carr, personal communication, August 3, 2015). The demographic composition of the intervention group compared to the control group was assessed for significant differences to account for differences in outcomes.

### **Inclusion Criteria**

Patients eligible for participation include a primary HF diagnosis, ability to speak English, may have a LVAD, have a wireless telephone capable of receiving text messaging for 30 days (adequate amount of data messaging or unlimited messaging on wireless plan), >18 years of ages, and the ability to be discharged home. Participants eligible for inclusion must be able to receive text messaging (one message received daily for 30 days) by allotting > 0.5 GB mobile data messaging through a wireless carrier of their choice.

### **Exclusion Criteria**

There was no exclusion based on sex/gender or racial/ethnic groups. Exclusion criteria that must be met included those participants who were unable to read and did not speak English. Also, those who were pregnant were excluded from the study.

## **Methods**

### **Recruitment**

Recruitment of subjects occurred through HF providers at the University of Kentucky including an Inpatient Acute Care Nurse Practitioner and Patient Care Facilitator who organized the needs of patients with HF who could be discharged from the hospital. Identification of patients who met the inclusion criteria was evaluated by these two members of the study team. They gave each eligible patient a flyer about the Smart Heart Self Care First Pilot Study (Appendix H). If the patient was interested in participating and would like more information, study personnel communicated this interest with the PI to enroll the patient in the study.

### **Informed Consent**

The PI was responsible for obtaining informed consent. Occasionally, there was a brief waiting period between determination of eligibility to participate in the study (by study personnel) and obtaining informed consent. This is because eligible participants were given a flyer by study personnel for them to decide if they were interested in participating in the study. Also, some patients were supposed to be discharged on a certain day but had complications that prolonged their hospital stay. Some patients were enrolled a few days prior to discharge compared to other subjects who were enrolled on the day of their discharge home. The consent process to participate in the SHSCF pilot study took approximately fifteen to thirty minutes on average. After consent was obtained, the PI gave a copy of the consent form with highlighted contact information to each participant.

The informed consent process also required explanation of the incentive to participate provided by the Health Education Library. This incentive included a daily weight calendar to track weight and HF symptoms, a pill calendar organizer (with morning, lunch, evening, and bedtime time frames), as well as the HF Core Measure Education packet for each participant.

**Data Collection Prior to Discharge**

Each participant received the standard of care for HF patients at discharge. This includes the option to obtain medications from the Chandler Retail Pharmacy prior to discharge as well as HF education labeled as “Heart Failure Core Measures Education” under the Krames education tab on the electronic medical record in Sunrise Clinical Manager.

After informed consent was obtained, the client was given a paper copy of a survey that evaluated comfort and use of text messaging from a mobile phone (See Appendix B). This survey was developed by modifying and incorporating questions from a study by Nundy et al. (2013) to determine if the participant had a smart phone, the average use of a cell phone (frequency), if the participant had an unlimited texting plan, had used text messaging in the past, and the number of texts received per day.

Next, a paper copy of the 1) PHQ-9 (Appendix C) 2) GAD-7 Scale (Appendix D) and 3) The Self-Care of Heart Failure Index tool (Appendix A) were given to the patient to fill out. Demographic information was obtained from the client’s electronic medical record as well as from a brief survey from the client with Appendix I (Demographic Information Form). For patients who did not have their glasses or had trouble writing, these tools were read aloud by the PI.

To ensure safety, if a participant scored  $\geq 10$  on the PHQ-9 or GAD-7, their provider was notified. A depression and anxiety symptom screening protocol (See Appendix G) was implemented to ensure follow-up of symptoms. This study resulted in one participant requiring psychiatric consultation due to thoughts of self-harm or harm to others. This delayed the participant’s discharge for up to 24 hours but they were not considered a harm to themselves and were sent home the next day.

**Procedures for the Intervention Group**

On the day of discharge, study personnel confirmed the participant's discharge from the hospital to home. Their "final discharge summary" was evaluated for discharge medications. The next day, the client would receive a message welcoming them to the SHSCF pilot program at 9:15 am. Then the client received one message every day for the next 30 days at the same time, 9:15 am each morning (See Appendix J). These texts included self-care information from HF patient teaching guide developed by the Robert Wood Johnson Foundation in 2011 that is a part of a national program called Expecting Success: Excellence in Cardiac Care (Bornstein et al., 2011).

**Data Collection Post Intervention**

On the 30<sup>th</sup> day after discharge, each participant in both the control and intervention groups received a telephone call to re-deliver the tools over the phone that were given prior to discharge 1) PHQ-9 (Appendix C) 2) GAD-7 Symptom Scale (Appendix D) and 3) SCHFI (Appendix A). Also, the MLWHFQ-21 (Appendix E) was administered at this point in time. This took approximately twelve minutes to one hour to collect the post intervention data. Several of the participants were not easily reachable and required multiple voicemails left by the PI to enhance communication. During the telephone interview, the PI confirmed any readmissions the client had during the 30 days immediately following discharge in addition to review of the electronic medical record. This was performed to capture any readmissions to an inpatient facility for HF outside of UK. Participants were then mailed a brief satisfaction survey (See Appendix F) to thank them for participation and gather feedback on the pilot study. An envelope with return postage was included with this satisfaction survey.

## **Data Analysis**

Descriptive analysis included means with standard deviations for continuous variables and frequencies with percentages for categorical and ordered categorical variables. Specifically, daily text messages received and discharge medications prescribed were described using frequencies and percentages. Differences in baseline demographic and study variables between the intervention and control groups were examined using Fischer's exact test for categorical data and independent sample t-tests (with Levene's test for equality of variances) for continuous variables. Changes in SCHFI, PHQ-9, GAD-7 scores were examined using paired sample t-tests. In addition, differences between the control and intervention groups in the MLWHFQ-21 scores were examined using independent sample t-tests at post intervention. Finally, differences in the number of 30 day readmissions between the intervention and the control group was examined using chi-square analysis. All data was analyzed using SPSS 22 and an alpha level of 0.05 was set for statistical significance in all analyses.

## **Results**

### **Sample Characteristics**

The sample was primarily male (70%), Caucasian (85%), urban (60%), mostly middle aged (mean age= 49.1, SD= 14.9) and not married (60%). On average, participants had a high school education or above (85%) and had a majority household income of <\$20,000 (70%). The majority of the sample was obese (mean body mass index=34.6, SD=11.9), had a New York Heart Association (NYHA) class greater than II (65%), and had a low left ventricular ejection fraction (LVEF) percentage (mean LVEF= 26.3%, SD=13.3). Thirty-percent of the sample had a left ventricular assist device (LVAD) and the majority (85%) had a non-preserved LVEF.

On average, participants had mild depression and anxiety symptoms (mean PHQ-9=7.2, SD=5.1; mean GAD-7=5.3, SD=5.6) of which 25% of the intervention and 33.3% of the control group had moderate to severe depression symptom scores; and 0% of the intervention and 25% of the control group had moderate to severe anxiety symptom scores. The sample had a mean HF self-care score of 61.5 (SD=11.9).

There were also significant differences between the intervention and control groups in educational level and NYHA class. At baseline, as compared to those in the control group, individuals in the intervention group were more likely to have a high school or greater education (100% vs. 75%,  $p=.02$ ) and less severe NYHA class I or II (37.5% vs. 83.4%,  $p=.04$ ). See Table 5 for details.

Data collected from the text messaging comfort survey (Appendix B) indicated that all participants owned a smart phone, could receive text messages, and had an adequate data plan that allowed them to receive the 30 texts if they were in the intervention group. All subjects know how to open and view a text message and most carried their phone frequently. The average daily use of text messaging is described in Figure 2. There was no significant difference between the control and intervention groups in texts received per day and how often the participant carried their phone with them.

Medications prescribed at discharge to over 75% of participants in the intervention and control groups included beta blockers, diuretics, and anticoagulants (See Figure 3). There were no differences between the control and intervention group in the medications prescribed at discharge. Recommendations by the Joint Commission include the prescription of a beta blocker and angiotensin converting enzyme (ACE) inhibitor, or angiotensin receptor blocker (ARB) if unable to take an ACE inhibitor, to reduce mortality and improve survival if the left ventricular

ejection fraction is < 40% at discharge (Gardetto & Carroll, 2007). The prescribing rate was >75% at discharge for both intervention and control groups for a beta blocker in comparison to ACE inhibitors or ARBs which was prescribed at a rate of less than 35%.

### **Changes in self-care, depression symptoms, and anxiety symptoms**

There were non-significant changes in self-care scores, depression symptom scores, and anxiety symptom scores from pre to post intervention (see Table 6). In the total sample, self-care scores increased from an average of 61.1 [SD=11.2] pre-intervention to 65.2 [SD=9.2] at post intervention; albeit, these increases were non-significant [ $t= 1.4$  (df=17),  $p= .19$ ). In the stratified analysis, similar non-significant increases were observed with the intervention group [Mean=65.7, SD= 11.7 to Mean= 67.6, SD=9.6] and the control group [Mean=58.2, SD= 10.3 to Mean= 63.6, SD=9.0] (see Figure 4).

In the total sample, depression symptom scores decreased from an average of 6.9 [SD=5.2] pre-intervention to 6.7 [SD=5.5] at post intervention; but, these decreases were non-significant [ $t= - 0.2$  (df=17),  $p= .86$ ). In the stratified analysis, similar non-significant decreases were observed with the intervention group [Mean=6.9, SD= 4.1 to Mean= 5.6, SD=2.6] compared to the control group which showed an increase in PHQ-9 scores [Mean=7.0, SD= 6.0 to Mean= 7.4, SD=6.8] (see Figure 5).

In the total sample, anxiety symptom scores increased from an average of 5.0 [SD=5.7] pre-intervention to 6.4 [SD=5.9] at post intervention; albeit, these increases were non-significant [ $t= 1.6$  (df=17),  $p= .14$ ). In the stratified analysis, similar non-significant increases were observed with the intervention group [Mean=2.4, SD= 3.1 to Mean= 4.0, SD=3.4] and the control group [Mean=6.6, SD= 6.5 to Mean= 7.9, SD=6.8] (see Figure 6).

**Differences in Quality of Life**

There were non-significant differences in MLWHFQ-21 scores between the intervention and control groups. After 30 days, the intervention group had lower scores in the MLWHFQ-21 as compared to the control group [Mean=47.7 (SD=10.6) vs. Mean= 55.4 (SD=9.9),  $p = .62$ ] (see Figure 7).

**Readmissions**

At 30-day follow-up, a total of 5 (20%; intervention group =2 vs. control group=3) participants had been readmitted to the hospital. There were no significant differences in 30 day readmissions between the intervention and the control group (25% vs. 25%).

**Discussion of Findings****Summary**

This pilot study is one of few studies to deliver a daily text-messaging intervention to HF patients to improve self-care and prevent readmissions. The use of telehealth technology proves to be a clinically relevant answer to a multifaceted approach to transitional care of patients from the hospital to home in patients with HF. Although there were no statistically significant changes or differences between the intervention and control group in all outcomes measures (self-care, depression symptoms, anxiety symptoms, hospital readmissions, and quality of life), they may have important implications for future research and nursing practice. This pilot study indicates that telehealth interventions such as daily text message reminders about self-care may be labeled as a HF management program that promote HF education with a goal of improved patient outcomes (Smeulders, van Haastregt, van Hoef, van Eijk, & Kempen, 2006).



**Depression and anxiety symptom prevalence**

Previous researchers have noted approximately one fifth to one third of patients with HF were found to have co-morbid depression or clinical symptoms of depression in addition to patients with anxiety levels above those of the average healthy adult (Heo & Moser et al., 2007; Dekker et al., 2014; Goodman et al., 2013; Volz et al., 2011; Suzuki et al., 2014; Damen, Pelle, Szabo, & Pederson, 2011; Alhurani et al., 2014; Shen et al., 2011; Staniute et al., 2015; Chung et al., 2009). These findings are comparable to this SHSCF pilot study because there was 25% and 33.3% incidence of moderate to severe depression symptoms in the intervention and control groups respectively. Although this pilot study did not have similar results for anxiety symptoms in the intervention group, the control group had a 25% incidence of moderate to severe anxiety symptoms; this is comparable to the research previously mentioned. Interestingly, in one study, HF patients with depression or depressive symptoms were more likely to experience anxiety symptoms than patients without depressive symptoms (Dekker et al., 2014). It is possible that with a larger sample, the proportion of participants who score moderate to severe on anxiety symptoms would increase and be comparable to other studies.

Furthermore, it is important to note the response of the providers who cared for the participants who scored moderate to severe in either depression or anxiety symptoms. Some of the participants were already on pharmacotherapy for previously known or diagnosed depression, anxiety, or mood disorders. However, the notification of providers of the scores on the PHQ-9 and GAD-7 did not trigger a dose increase or counseling of the HF provider. This is particularly enthralling because it indicates that providers in the acute care setting may not feel comfortable prescribing these types of medications. Alternatively, acute care providers may see mental health symptoms as a primary care issue for outpatient followed up. This area needs further exploration

to determine the attitudes and beliefs of providers caring for the HF population on mental health in this patient population.

### **Self-care, depression symptoms, and anxiety symptoms**

The SHSCF pilot program showed that there were changes in self-care, depression symptom, and anxiety scores measured between prior to discharge and at the 30-day follow-up. Specifically, in the intervention and control groups, depression symptom scores decreased, anxiety scores increased and self-care scores increased, all, though statistically non-significant, may be clinically significant.

In terms of the observed increase in self-care scores, it is not surprising that the telehealth methods in this pilot study produced such a positive effect. According to Ditewig, Blok, Havers & van Veenendaal (2010), patient education is used frequently in HF self-management programs, especially to help patients recognize signs and symptoms of decompensation early enough to seek help from a medical professional. Furthermore, programs that included telemonitoring or HF management programs centered around education often result in improved self-care behaviors, increased self-efficacy, and helped participants to feel more accountable for their care (Baker et al., 2011; Ciere et al., 2012; Radhakrishnan & Jacelon, 2012; Seto et al., 2012). Several researchers have stressed the importance of patient education on self-care (Stromberg, 2005; Gonseth, Guallar-Castillon, Banegas, and Rodriguez-Artalelo, 2004; Gwadry-Sridhar, Flintoft, Lee, Lee, and Guyatt, 2004; McAllister, Lawson, Teo, and Armstrong, 2001) but note that education alone is not sufficient to improve self-management skills. Thus, the findings from this pilot study are congruent with current research on HF self-care and suggest a need for more evidence related to telehealth interventions.

Furthermore, in the intervention group, depression symptom scores decreased compared to those participants in the control group whose scores increased albeit non-significantly. It is well understood that the co-morbid presence of depression in HF patients may impact patient treatment adherence and self-management. Preventing the progression or worsening of HF is often centered on medical management including pharmacotherapies in this patient population; this has been reported to have a negative correlation with depression (Morgan et al., 2006). Patients who have depression symptoms and HF are significantly less likely to adhere to their medication regimen (Morgan et al., 2006). Additionally, other self-care activities such as dietary modification and physical functioning may be improved with interventions that target depression symptoms in this population (Riegel et al., 2009; Rutledge, Reis, Linke, Greenberg, & Mills, 2006; Dusseldorp, van Elderen, Meulman, & Kraaij, 1999). Some researchers suggest that depression may inhibit optimal self-care activities and that poor self-care is related to depression symptoms (Cameron, Worrall-Carter, Page, Riegel, Lo, & Stewart, 2010; Morgan et al., 2006; Riegel, Vaughan Dickson, Goldberg, & Deatrck, 2007). Hence, interventions targeting patients with HF who have depression and poor self-care may result in better outcomes than just focusing on either depression or self-care alone (Riegel et al., 2009). This evidence highlights the importance of this pilot study because it combines both the knowledge of self-care skills with screening for depression symptoms.

It has been noted that research in HF patients who also have anxiety is limited. In the scientific statement from the American Heart Association on the promotion of self-care in persons with HF, researchers suggest that the presence of anxiety is likely to negatively impact self-care (Riegel et al., 2009). This may be due to symptoms such as generalized fatigue or exhaustion, impaired concentration, muscle tension, insomnia or sleeping difficulties, and irritability that prevent the engagement in self-care tasks (American Psychiatric Association, 2013, p. 222). It is

worth mentioning that anxiety has been found to contribute to a higher poor functional status and more physical symptoms in patients with chronic medical conditions even after controlling for severity of disease (Katon, Lin, & Kroenke, 2007). Recently, high levels of anxiety were reported to have a negative association with self-care management in HF patients; those patients also indicated a decreased likelihood to consult their providers for medical advice as well (Lee et al., 2015). Thus, there may be delayed provider communication as well as self-care skills that contribute to poorer clinical outcomes. With limited knowledge about anxiety in HF populations, future studies should focus on the relationship between Anxiety symptoms and self-care behaviors.

### **Quality of Life**

This study found that there was no significant difference in quality of life between the intervention and control groups. It is well known that there is a negative association between depression, anxiety, and quality of life in patients with HF compared to healthy aging adults (Heo & Moser et al, 2007; Goodman, Firouzi, Banya, Lau-Walker, & Cowie, 2013; Hallas, Wray, Andreou, & Banner, 2011; Serafini et al., 2013; Nesbitt et al., 2014; Cully, Phillips, Kunik, Stanley, & Deswal, 2010; Paukert, LeMaire, & Cully, 2009; Heo, Doering, Widener, & Moser, 2008; Shen et al., 2011; Staniute et al., 2015; Chung et al., 2009). Reduced quality of life indicated by a high score on the MLWHFQ-21 suggests that those patients with depression or anxiety symptoms are consequently less likely to adapt to changes in behavior resulting in poorer self-care (Albert & Zeller, 2009; Hallas et al., 2011). Furthermore, the presence of psychological comorbidities may distort the expectation of the illness and amplify the severity of disease, leading to reduced self-care and inability to cope with the diagnosis of HF (Goodman et al., 2013).

**Readmissions**

The findings regarding readmissions demonstrated that there was no difference in hospital readmissions for the intervention and control groups 30 days after discharge. It is noted that none of the participants readmitted in the intervention group had a primary diagnosis of HF decompensation upon return to the hospital; these readmissions were attributed to bleeding complications from the participants LVAD and ventricular dysrhythmias requiring electrical defibrillation. Comparatively, two of the three patients readmitted within the control group were related to HF exacerbations. This finding is interesting because it may suggest that the intervention group may have positively benefitted from HF education because of improved self-care; there were less readmissions related to HF decompensation in the intervention group compared to the control group. Previous studies have noted that HF related hospitalizations were reduced in patients who were part of a telemonitoring or telehealth intervention study (Austin et al., 2012; Baker et al., 2011; Chaudhry et al., 2010; Dendale et al., 2012; Feltner et al., 2014; Inglis et al., 2011; Koehler et al., 2011; Kurtz et al., 2011; Schmidt et al., 2010; Seto et al., 2012; Weintraub et al., 2010). Given the limited sample size for this pilot study, a larger, better powered study is needed to further determine the effects of telehealth interventions on HF related readmissions.

**Patient Satisfaction**

Overall, the SHSCF pilot study was well received by participants. The participants in the intervention group had positive reflections about the program and the information it provided about self-care skills and management. Even if participants verbalized that they already knew the information, they noted an enhanced comfort in their confidence about the information as well as improved positivity and optimism. Text messages were evaluated for the preferred time of day but most participants did not see the need to change the timing. The biggest complaint about the

program was that participants found it difficult to complete the telephone survey at the 30-day follow-up and would have preferred a mailed hard copy of the forms instead. However, there was a 90% follow-up rate so it is possible that a mailed copy of the forms could be used as an alternative method if telephone interview was not achievable.

### **Feasibility of Study**

There are many areas of improvement for this pilot program. These areas include study design, participant recruitment and enrollment, and post intervention follow-up.

### **Controlling for Differences in the Control vs. Intervention Group**

Due to significant differences in the control and intervention group for educational level and HF class, it may have been beneficial to stratify the sample by NYHA Class. Perhaps, half of each group would have the same number of participants with NYHA class I-II and the other half have NYHA class III-IV in both the intervention and control groups. This may have impacted the average score for the PHQ-9 and the GAD-7 since patients with advanced disease may be more likely to have depression and anxiety symptoms. Additionally, controlling for educational level may have impacted SCHFI scores. The mean SCHFI score of the sample was higher than expected (mean SCHFI= 61.5, SD=11.9) and may be related to a higher educational level in the intervention group.

### **Timeline**

This pilot program projected a potential sample size of 50 participants. A power analysis was not required given that this was a pilot feasibility study. The sample size of fifty was chosen to match the average monthly discharge rate of HF patients at the University of Kentucky. However, only 20 patients were enrolled in the pilot study due to time constraints. For a future

study, a power analysis should be performed by potentially using the preliminary findings of this study. Such a powered study could make the study's conclusions more meaningful.

### **Text Messaging Delivery**

The website used for delivery of the HF self-care text messages was not reliable. There were 3 separate occasions in which the website had downtime and was not actively delivering text messages. The first time this occurred was when the only participant in the intervention group was receiving text messages. The website was unavailable for 48 hours and was successfully back up the following Monday. This could have been because it occurred over the weekend. There was another instance where the website was down for less than 24 hours affecting, 4 participants; those participants missed 1 message. At this point during the pilot, there was decreased response time from the website host about ensuring delivery of the text messages. Finally, the last time the website was unavailable was for five days, affecting 5 participants. The participants still received all messages but there was a gap in the messages of 5 days. Those participants were followed up with post self-care, depression, and anxiety scores after they completed the intervention (although it was longer than 30 days). It was decided to switch website hosts at this point to ensure adequate dosing of the intervention. The new website host had great customer service and was costlier. It would have been beneficial to choose a more expensive host in the beginning of the study to prevent technology failures.

### **Inclusion Criteria: Ownership of a Cell Phone**

As mentioned earlier, many participants were excluded due to the inability to receive text messages on a cellular phone or the lack of a smart phone. Perhaps the use of text messaging through Apple, Android, or Microsoft tablets could have allowed certain eligible patients to participate in the study if this option was available. Also, funding available to purchase “go-

phones” could have allowed the inclusion of more patients. Grant funding would have improved the number of participants eligible to participate in the study.

**Single Institution**

The results found from this pilot study are applicable to academic medical centers who offer similar therapies for advanced HF including LVADs, extracorporeal membrane oxygenation (ECMO), milrinone therapy, inhaled Flolan, and transplantation. The pilot feasibility study limits the generalization to a patient sample in a rural setting compared to the urban, academic center in which patients are referred from across the region.

**Recruitment**

This study did not recruit from other services outside of Cardiology. This could have led to an under-inclusion of eligible participants located on internal medicine teams or in medical intensive care units in other areas of the hospital.

**Enrollment**

Although the study personnel included many people, the PI was the only person to enroll patients for the program. This often times, was very time consuming especially if a patient did not have their glasses to read the outcomes tools or had trouble hearing. The enrollment process took on average approximately 40 minutes to over an hour to complete. This was due to interruptions in the delivery of informed consent as well as the time it took for the participant to fill out the tools. Interruptions in enrollment are anticipated and included visits from home health agencies delivering equipment (oxygen tanks, walkers, canes, shower equipment), members of the patient care team (physicians, nurse practitioners, nurses, pharmacists, physical therapists, occupational therapists), and other companies such as Infusion partners (sets up home milrinone infusions) or LifeVest representatives. It may have been easier to collect data from the



tools on an iPad and have everything stored in REDCap (Research Electronic Data Capture) for easy access; this is a secure, web-based application designed exclusively to support data capture for research studies. This also would have avoided manual data entry that could result in unintended data entry error.

### **Follow-up**

Thirty days after discharge, each patient was interviewed by telephone to collect post intervention data for self-care, depression symptoms, and anxiety symptoms. They were also administered the MLWHFQ-21 to assess quality of life which contributed to a lengthy conversation. For some, the phone calls lasted 12 minutes at minimum to a maximum time of 1 hour or more. It was noted in the patient satisfaction survey that it would have been easier to fill out the forms again in person if the surveys were sent to each participant by mail. Also, the use of electronic research data capture software such as REDCap or Survey Monkey could have promoted follow up response for those participants who are younger and do not converse on the phone regularly.

### **Limitations**

There were several limitations for this study which, when addressed, can contribute to the better design of future studies that use telehealth technology. First, patients recruited for the study were unable to be a part of other research studies or join a study after enrollment in the SHSCF pilot program. This limited the sample population for the study and often prevented participants from enrolling. During the first 3 weeks of this pilot, recruitment for the study was low so the protocol was modified to include patients with LVADs. This was not optimal considering that patients with LVADs have special access and support from nurse coordinators compared to those patients whose HF is not advanced enough to require mechanical device

support therapy. This may have contributed to a moderately high average SCHFI score of 61.5 out of 100 possible points which was higher than expected. This may indicate a falsely high self-care score if those patients who have LVADs score higher on the SCHFI tool. However, it is likely that the majority of the education given to LVAD patients by their coordinators is mostly device related.

Other problems related to the recruitment and enrollment of patients include the lack of a cellular device or data service to receive the daily text messaging intervention. This limited the population that met inclusion criteria and contributed to the small sample size of the pilot program. Disadvantages, including absent study personnel to recruit participants as well as a single institution, also contributed to the small sample size and limit generalizability of findings.

Second, it is possible that the average depression and anxiety scores (mean PHQ-9=7.2; mean GAD-7= 5.3) indicating mild symptoms were related to the Hawthorne effect. The Hawthorne effect explains how a person's behavior or responses can change when they know they are being observed. With sensitive issues such as the question about thoughts of self-harm or harm to others on the PHQ-9, it is possible that participants may be reluctant to answer truthfully. It is noteworthy that the design of this protocol included requirements set forth by the Institutional Review Board (IRB) to ensure patient safety. This means that in the informed consent form, each participant was notified that if they scored moderate, moderately high, or severe on the PHQ-9 or the GAD-7 their provider would be notified. The risks and possible outcomes of these scores were also described thoroughly to teach patient per protocol. The possibilities outlined included the start of new medications, initiation of counseling, or consultation of Psychiatric services that would be the financial responsibility of the participant. This could have been a barrier to the participant answering questions about depression and

anxiety symptoms openly and honestly due to certain determinants of health such as socioeconomic status or access to care.

Other limitations included differences in education and NYHA class between the intervention and control group. Controlling for these variables, particularly NYHA class may have produced different results on self-care in addition to impacting depression and anxiety symptom scores. This can be attributed to the worsened functional status and increase symptoms experienced by persons with advanced HF; this is likely to affect psychological outcomes such as depression, anxiety, and quality of life.

The final limitation to the study was the missing data from two participants after the 30-day period post discharge. One participant, in the control group, unexpectedly died and the other participant, in the intervention group, was unable to be reached by telephone. It is unlikely that this would have contributed to statistical significance of the study findings, though, because of the overall small study sample size.

### **Conclusion**

Self-management programs such as the SHSCF pilot program offer hope to providers and patients as they transition from an acute care facility to home. Specifically, telehealth methods show promise in increasing provider and patient communication as well as access to specialty care. This program highlights how the routine screening for depression and anxiety symptoms could be beneficial in the HF population at the time of discharge. Encompassing a holistic approach to care through the evaluation of emotional, and not just physical, health is important to overall health and wellness. This pilot study laid the foundation for designing and implementing a larger study in the future. Findings from this study help to emphasize that HF self-management programs are multifaceted and incorporate many elements that promote self-care.

## References

- Albert, N., & Zeller, R. (2009). Depressed patients understand heart failure prognosis but not how to control it. *Heart & Lung*, 38(5), 382-391. doi: 10.1016/j.hrtlng.2008.10.007
- Americana Psychiatric Association (2013). Diagnostic and statistical manual of mental disorders: Fifth edition. Arlington, VA: American Psychiatric Publishing.
- Austin, L. S., Landis, C. O., & Hanger, K. H., Jr. (2012). Extending the continuum of care in congestive heart failure: an interactive technology self-management solution. *Journal of Nursing Administration*, 42(9), 442-446. doi: 10.1097/NNA.0b013e3182668342
- Baker, D. W., Dewalt, D. A., Schillinger, D., Hawk, V., Ruo, B., Bibbins-Domingo, K., . . . Pignone, M. (2011). The effect of progressive, reinforcing telephone education and counseling versus brief educational intervention on knowledge, self-care behaviors and heart failure symptoms. *Journal of Cardiac Failure*, 17(10), 789-796. doi: 10.1016/j.cardfail.2011.06.374
- Bornstein, T., Brown, B., Goodell, D., Gutierrez, M., John, J., Matutes-Eckhardt, A., McDowell, E., Pont, A., & Stubbs, F. Living with heart failure: A patient teaching guide. *Expecting Success: Excellent in Cardiac Care*, 1-29. Retrieved from <http://www.rwjf.org/content/dam/supplementary-assets/2008/06/Heart-Failure-Patient-Teaching-Guide-2011.pdf>
- Cameron, O., Abelson, J., & Young, E. (2004). Anxious and depressive disorders and their comorbidity: Effect on central nervous system noradrenergic function. *Biological Psychiatry*, 56(11), 875-883. Doi: 10.1016/j.biopsych.2004.08.007
- Cameron, J., Worrall-Carter, L., Page, K., Riegel, B., Lo, S., & Stewart, S. (2010). Does cognitive impairment predict poor self-care in patients with heart failure? *European Journal of Heart Failure*, 12(5), 508-515. Doi: 10.1093/eurjhf/hfq042

- Centers for Disease Control and Prevention. (2016). *Heart Failure Fact Sheet*. Retrieved from [http://www.cdc.gov/dhdsdp/data\\_statistics/fact\\_sheets/fs\\_heart\\_failure.htm](http://www.cdc.gov/dhdsdp/data_statistics/fact_sheets/fs_heart_failure.htm)
- Chaudhry, S., Mattera, J., Curtis, J., Spertus, J., Herrin, J., Lin, Z., Phillips, C., Hodshon, B., Cooper, L., & Krumholz, H. (2010). Telemonitoring in patients with heart failure. *New England Journal of Medicine*, 363(24), 2301-2309. doi: 10.1056/NEJMoa1010029
- Chung, M., Moser, D., Lennie, T., & Rayens, M. (2009). The effects of depressive symptoms and anxiety on quality of life in patients with heart failure and their spouses: Testing dyadic dynamics using Actor-Partner Interdependence Model. *Journal of Psychosomatic Research*, 67(1), 29-35. Doi: 10.1016/j.jpsychores.2009.01.009
- Ciere, Y., Cartwright, M., & Newman, S. P. (2012). A systematic review of the mediating role of knowledge, self-efficacy and self-care behaviour in telehealth patients with heart failure. *Journal of Telemedicine and Telecare*, 18(7), 384-391. doi: 10.1258/jtt.2012.111009
- Cully, J., Phillips, L., Kunik, M., Stanley, M., & Deswal, A. (2010). Predicting quality of life in veterans with heart failure: The role of disease severity, depression, and co-morbid anxiety. *Behavioral Medicine*, 36, 70-76. Doi: 10.1080/08964280903521297
- Damen, N., Pelle, a., Szabo, B., & Pedersen, S. (2011). Symptoms of anxiety and cardiac hospitalizations at 12 months in patients with heart failure. *Journal of General Internal Medicine*, 27(3), 345-350. Doi: 10.1007/s11606-011-1843-1
- Dekker, R., Lennie, T., Doering, L., Chung, M., Wu, J., & Moser, D. (2014). Coexisting anxiety and depressive symptoms in patients with heart failure. *European Journal of Cardiovascular Nursing*, 13(2), 168-176. Doi: 10.1177/1474515113519520
- Dendale, P., De Keulenaer, G., Troisfontaines, P., Weytjens, C., Mullens, W., Elegeert, I., . . . Hansen, D. (2012). Effect of a telemonitoring-facilitated collaboration between general

- practitioner and heart failure clinic on mortality and rehospitalization rates in severe heart failure: the TEMA-HF 1 (TElemonitoring in the MAnagement of Heart Failure) study. *European Journal of Heart Failure*, 14(3), 333-340. doi: 10.1093/eurjhf/hfr144
- Ditewig, J., Blok, H., Havers, J., and van Veenendaal, H. (2010). Effectiveness of self-management interventions on mortality, hospital readmissions, chronic heart failure hospitalization rate and quality of life in patients with chronic heart failure: A systematic review. *Patient Education and Counseling*, 78(3), 297-315. Doi: 10.1016/j.pec.2010.01.016
- Dusseldorp, E., van Elderen, T., Maes, S., Meulman, J., & Kraaij, V. (1999). A meta-analysis of psychoeducational programs for coronary heart disease patients. *Health Psychology*, 18(5), 506-519.
- Emory Healthcare. (2016). *Heart failure statistics*. Retrieved from <http://www.emoryhealthcare.org/heart-failure/learn-about-heart-failure/statistics.html>
- Feltner, C., Jones, C., Cene, C., Zheng, Z., Sueta, C., Coker-Schwimmer, E., Arvanitis, M., Lohr, K., Middleton, J., & Jonas, D. (2014). Transitional care interventions to prevent readmissions for persons with heart failure: a systematic review and meta-analysis. *Annals of Internal Medicine*, 160(11), 774-784. doi: 10.7326/M14-0083
- Gardetto, N. & Carroll, K. (2007). Management strategies to meet the core heart failure measures for acute decompensated heart failure: A nursing perspective. *Critical Care Nursing Quarterly*, 30(4), 307-320. Doi: 10.1097/01.CNQ.0000290364.57677.56
- Garin, O., Herdman, M., Vilagut, G., Ferrer, M., Rivera, A., Rajmil, L., Valderas, J., Guillemin, F., Revicki, D., & Alonso, J. (2014). Assessing health-related quality of life in patients

- with heart failure: a systematic, standardized comparison of available measures. *Heart Failure Review*, 19, 359-367. Doi: 10.1007/s10741-013-9394-7
- Gonseth, J., Guallar-Castillon, P., Banegas, J., and Rodriguez-Artalelo, F. (2004). The effectiveness of disease management programmes in reducing hospital re-admission in older patients with heart failure: A systematic review and meta-analysis of published reports. *European Heart Journal* (18), 1570-1590. Doi: 10.1016/j.ehj.2004.04.022
- Goodman, H., Firouzi, A., Banya, W., Lau-Walker, M., & Cowie, M. R. (2013). Illness perception, self-care behaviour and quality of life of heart failure patients: A longitudinal questionnaire survey. *International Journal Of Nursing Studies*, 50(7), 945-953. doi:10.1016/j.ijnurstu.2012.11.007
- Gwadry-Sridhar, F., Flitoft, V., Lee, D., Lee, H., and Guyatt, G. (2004). A systematic review and meta-analysis of studies comparing readmission rates and mortality rates in patients with heart failure. *Archives of Internal Medicine*. 164(21), 2315-2320. Doi: 10.1001/archinte.164.21.2315
- Hallas, C. N., Wray, J., Andreou, P., & Banner, N. R. (2011). Depression and perceptions about heart failure predict quality of life in patients with advanced heart failure. *Heart & Lung*, 40(2), 111-121. doi:10.1016/j.hrtlng.2009.12.008
- Hammash, M., Hall, L., Lennie, T., Heo, S., Chung, M., Lee, S., & Moser, D. (2013). Psychometrics of the PHQ-9 as a measure of depressive symptoms in patients with heart failure. *European Journal of Cardiovascular Nursing*, 12(5), 446-453. Doi: 10.1177/1474515112468068
- Hammash, M., Lennie, T., Crawford, T., Heo, S., Chung, M., Biddle, M., Dekker, R., Wu, J., Rayens, M., & Moser, D. (2016). Depressive symptoms: Mediator of event-free survival

- in patients with heart failure. *Western Journal of Nursing Research*, 1-14. Doi: 10.1177/0193945916658883
- Heo, S., Doering, L., Widener, J., & Moser, D. (2008). Predictors and effect of physical symptom status on health-related quality of life in patients with heart failure. *American Journal of Critical Care*, 17(2), 124-132.
- Heo, S., Moser, D., Lennie, T., Zambroski, C., & Chung, M. (2007). A comparison of health-related quality of life between older adults with heart failure and healthy older adults. *Heart & Lung*, 36(1), 16-24.
- Holsboer, F. & Ising, M., (2008). Central CRH system in depression and anxiety-Evidence from clinical studies with CRH1 receptor antagonists. *European Journal of Pharmacology*, 583(2-3), 350-357. Doi: 10.1016/j.ejphar.2007.12.032
- Inglis, S. C., Clark, R. A., McAlister, F. A., Stewart, S., & Cleland, J. G. (2011). Which components of heart failure programmes are effective? A systematic review and meta-analysis of the outcomes of structured telephone support or telemonitoring as the primary component of chronic heart failure management in 8323 patients: Abridged Cochrane Review. *European Journal of Heart Failure*, 13(9), 1028-1040. doi: 10.1093/eurjhf/hfr039
- Jaarsma, T., Stromberg, A., Ben Gal, T., Cameron, J., Driscoll, A., Duengen, H. D., . . . Riegel, B. (2013). Comparison of self-care behaviors of heart failure patients in 15 countries worldwide. *Patient Education and Counseling*, 92(1), 114-120. Doi: 10.1016/j.pec.2013.02.017
- James, J. (2013). Patient engagement. *Health Policy Briefs*, 35(11). Retrieved from [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=86](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=86)



- Katon, W., Lin, E., & Kroenke, K. (2007). The association of depression and anxiety with medical symptom burden in patients with chronic medical illness. *General hospital Psychiatry*, 29(2), 147-155. Doi: 10.106/j.genhsoppsych.2006.11.005
- Koehler, F., Winkler, S., Schieber, M., Sechtem, U., Stangl, K., Bohm, M., Boll, H., Baumann, G., Honold, M., Koehler, K., Gelbrich, G., Kirwan, B., Anker, S. (2011). Impact of remote telemedical management on mortality and hospitalizations in ambulatory patients with chronic heart failure: the telemedical interventional monitoring in heart failure study. *Circulation*, 123(17), 1873-1880. doi: 10.1161/CIRCULATIONAHA.111.018473
- Kroenke, Spitzer, Williams, & Lowe. (2010). The patient health questionnaire somatic, anxiety, and depressive symptoms scales: A systematic review. *General Hospital Psychiatry*, 32(4), 345-359. doi: 10.1016/j.genhosppsy.2010.03.006
- Kurtz, B., Lemercier, M., Pouchin, S. C., Benmokhtar, E., Vallet, C., Cribier, A., & Bauer, F. (2011). Automated home telephone self-monitoring reduces hospitalization in patients with advanced heart failure. *Journal of Telemedicine and Telecare*, 17(6), 298-302. doi: 10.1258/jtt.2011.100901
- Lee, C., Gelow, J., Mudd, J., Green, J., Hiatt, S., Chien, C., & Riegel, B. (2015). Profiles of self-care management versus consulting behaviors in adults with heart failure . *European Journal of Cardiovascular Nursing*, 14(1), 63-72. Doi: 10.1177/1474515113519188
- Lee, C. S., Lyons, K. S., Gelow, J. M., Mudd, J. O., Hiatt, S. O., Nguyen, T., & Jaarsma, T. (2013). Validity and reliability of the European Heart Failure Self-care Behavior Scale among adults from the United States with symptomatic heart failure. *European Journal of Cardiovascular Nursing*, 12(2), 214-218. doi: 10.1177/1474515112469316

- Leo, R., Di Lorenzo, G., Tesauro, M., Razzini, C., Forleo, G., Chiricolo, G., Cola, C., Zanasi, M., Troisi, A., Siracusano, A., Lauro, R., & Romeo, F. (2006). Association between enhanced soluble CD40 ligand and proinflammatory and prothrombotic states in major depressive disorder: pilot observations on the effects of selective serotonin reuptake inhibitor therapy. *The Journal of Clinical Psychiatry*, 67(11), 1760-1766.
- Licht, C., de Geus, E., van Dyck, R., & Penninx, B. (2009). Association between anxiety disorders and heart rate variability in the Netherlands Study of Depression and Anxiety (NESDA). *Psychosomatic Medicine*, 71(5), 508-518. Doi: 10.1097/PSY.0b013e3181a292a6
- Licht, C., de Geus, E., Zitman, F., Hoogendijk, W., van Dyck, R., & Penninx, B. (2008). Association between major depressive disorder and heart rate variability in the Netherlands Study of Depression and Anxiety (NESDA). *Archives of General Psychiatry*, 65(12), 1358-1367. Doi: 10.1001/archpsyc.65.12.1358
- Morgan, A., Masoudi, F., & Havranek, E., Jones, P., Peterson, P., Krumholz, H., Spertus, J., & Rumsfeld, J. (2006). Difficulty taking medications, depression, and health status in heart failure patients. *Journal of Cardiac Failure*. 12(1), 54-60. Doi: 10.1016/j.cardfail.2005.08.004
- Lloyd-Jones, D., Hong, Y., Labarthe, D., Mozaffarian, D., Appel, L., Van Horn, L., Greenlund, K., Daniels, S., Nichol, G., Tomaselli, G., Arnett, D., Fonarow, G., Ho, M., Lauer, M., Masoudi, F., Robertson, R., Roger, V., Schwamm, L., Sorlie, P., Yancy, C., Rosamond, W. (2010). Defining and setting national goals for cardiovascular health promotion and disease reduction: The American heart association's strategic impact goal through 2020 and beyond. *Circulation*, 121, 586-613. Doi: 10.1161/CIRCULATIONAHA.109.192703

- McAllister, F., Lawson, F., Teo, K., and Armstrong, P. (2001). A systematic review of randomized trials of disease management programs in heart failure. *American Journal of Medicine*, 110(5), 378-384. Doi: 10.1016/S0002-9343(00)00743-9
- Morel-Kopp, M., McLean, L., Chen, Q., Tofler, G., Tennant, C., Maddison, V., & Ward, C. (2009). The association of depression with platelet activation: evidence for a treatment effect. *Journal of Thrombosis and Haemostasis: JTH*, 7(4), 573-581. Doi: 10.1111/j.1538-7836.2009.03278.x.
- Morgan, A., Masoudi, F., Havranek, E., Jones, P., Peterson, P., Krumholz, H., Spertus, J., & Rumsfeld, J. (2006). Difficulty taking medications, depression, and health status in heart failure patients. *Journal of Cardiac Failure*, 12(1), 54-60. Doi: 10.1016/j.cardfail.2005.08.004
- Nesbitt, T., Sahar, D., Southard, J., Singh, S., Fekete, A., Marie, K., Moser, D., Pelter, M., Robinson, S., Wilson, M., Cooper, L., & Dracup, K. (2014). Correlates of quality of life in rural patients with heart failure. *Circulation Heart Failure* 7(6), 882-887. Doi: 10.1161/CIRCHEARTFAILURE.113.000577
- Nundy, S., Razi, R., Dick, J., Smith, B., Mayo, A., O'Connor, A., & Meltzer, D. (2013). A text messaging intervention to improve heart failure self-management after hospital discharge in a largely African American population: Before-after study. *Journal of Medical Internet Research*, 15(3), e53. Retrieved from <http://www.jmir.org/2013/3/e53/>
- Paukert, A., LeMaire, A., & Cully, J. (2009). Predictors of depressive symptoms in older veterans with heart failure. *Aging & Mental Health*, 13(4), 601-610. Doi: 10.1080/13607860802459823

- Polikandrioti, M., Goudevenos, J., Michalis, L., Koutelekos, J., Kyristi, H., Tzialas, D., & Elisaf, M. (2015). Factors associated with depression and anxiety of hospitalized patients with heart failure. *Hellenic Journal of Cardiology*, 56(1), 26-35. Retrieved from [http://www.hellenicjcardiol.org/archive/full\\_text/2015/1/2015\\_1\\_26.pdf](http://www.hellenicjcardiol.org/archive/full_text/2015/1/2015_1_26.pdf)
- Radhakrishnan, K., & Jacelon, C. (2012). Impact of telehealth on patient self-management of heart failure: a review of literature. *Journal of Cardiovascular Nursing*, 27(1), 33-43. doi: 10.1097/JCN.0b013e318216a6e9
- Riegel, B. & Dickson, V. (2008). A situation-specific theory of heart failure self-care. *Journal of Cardiovascular Nursing*. 23(3), 190-196. Doi: 10.1097/01.JCN.0000305091.35259.85
- Riegel, B., Moser, D., Anker, S., Appel, L., Dunbar, S., Grady, K., Gurvitz, M., Havranek, E., Lee, C., Lindenfeld, J., Peterson, P., Pressler, S., Schocken, D., & Whellan, D. (2009). State of the science: Promoting self-care in persons with heart failure: a scientific statement from the American Heart Association. *Circulation*, 120(12), 1141-1163. doi: 10.1161/CIRCULATIONAHA.109.192628
- Riegel, B., Vaughan Dickson, V., Goldberg, L., & Deatrck, J. (2007). Factors associated with the development of expertise in heart failure self-care. *Nursing Research*, 56(4), 235-43. Doi: 10.1097/01.NNR.0000280615.75447.f7
- Rutledge, T., Reis, V., Linke, S., Greenberg, B., & Mills, P. (2006). Depression in heart failure: a meta-analytic review of prevalence, intervention effects, and associations with clinical outcomes. *Journal of American College of Cardiology*, 48(8), 1527-1537. Doi: 10.1016/j.jacc.2006.06.055

- Schmidt, S., Schuchert, A., Krieg, T., & Oeff, M. (2010). Home telemonitoring in patients with chronic heart failure: a chance to improve patient care? *Dtsch Arztebl Int*, 107(8), 131-138. doi: 10.3238/arztebl.2010.0131
- Serafini, G., Pompili, M., Innamorati, M., Iacorossi, G., Cuomo, I., Della Vista, M., Lester, D., De Biase, L., Girardi, P., Tatrelli, R. (2010). The impact of anxiety, depression, and suicidality on quality of life and functional status of patients with congestive heart failure and hypertension: An observational cross-sectional study. *Primary Care Companion Journal of Clinical Psychiatry*, 12(6). Doi: 10.4088/PCC.09m00916gry
- Shen, B., Eisenberg, S., Maeda, U., Farrell, K., Schwarz, E., Penedo, F., Bauerlein, E., & Mallon, S. (2011). Depression and anxiety predict decline in physical health functioning in patients with heart failure. *Annals of Behavioral Medicine*, 41(3), 373-382. Doi: 10.1007/s12160-010-9251-z
- Seto, E., Leonard, K. J., Cafazzo, J. A., Barnsley, J., Masino, C., & Ross, H. J. (2012). Mobile phone-based telemonitoring for heart failure management: a randomized controlled trial. *Journal of Medical Internet Research*, 14(1), e31. doi: 10.2196/jmir.1909
- Smeulders, E., van Haastregt, J., van Hoef, E., van Eijk, J., & Kempen, G. (2006). Evaluation of a self-management programme for congestive heart failure patients: Design of a randomized controlled trial. *BMC Health Services Research*, 6(91), 1-10. doi: 10.1186/1472-6963-6-91.
- Staniute, M., Brozaitene, J., Burkauskas, J., Kazukaukiene, N., Mickuviene, N., & Bunevicius, R. (2015). Type D personality, mental distress, social support, and health-related quality of life in coronary artery disease patients heart failure: a longitudinal observational study. *Health and Quality of Life Outcomes*, 13(1), 1-11. Doi: 10.1186/s12955-014-0204-2

- Suzuki, T., Shiga, T., Kuwahara, K., Kobayashi, S., Suzuki, S., Nishimura, K., Suzuki, A., Minami, Y., Ishigooka, J., Kasanuki, H., & Hagiwara, N. (2014). Impact of clustered depression and anxiety on mortality and rehospitalization in patients with heart failure. *Journal of Cardiology*, 64, 456-462. Doi: 10.1016/j.jjcc.2014.02.031
- Stromberg, A. (2005). The crucial role of patient education in heart failure. *European Journal of Heart Failure*, 7(3), 363-369. Doi: 10.1016/j.ejheart.2005.01.002
- Thomas, S., Chapa, D., Friedmann, E., Durden, C., Ross, A., Ching, M., & Lee, H. (2008). Depression in patients with heart failure: Prevalence, pathophysiologic mechanisms, and treatment. *Critical Care Nurse*, 28(2), 40-55.
- Volz, A., Schmid, J., Zwahlen, M., Kohls, S., Saner, H., & Barth, J. (2011). Predictors of readmission and health related quality of life in patients with chronic heart failure: A comparison of different psychosocial aspects. *Journal of Behavioral Medicine*, 34, 13-22. Doi: 10.1007/s10865-010-9282-8
- Weintraub, A., Gregory, D., Patel, A. R., Levine, D., Venesy, D., Perry, K., . . . Konstam, M. A. (2010). A multicenter randomized controlled evaluation of automated home monitoring and telephonic disease management in patients recently hospitalized for congestive heart failure: the SPAN-CHF II trial. *Journal of Cardiac Failure*, 16(4), 285-292. doi: 10.1016/j.cardfail.2009.12.012
- Zafar, M., Paz-Yepes, M., Shimbo, D., Vilahur, G., Burg, M., chaplin, W., Fuster, V., Davidson, K., & Badimon, J. (2010). Anxiety is a better predictor of platelet reactivity in coronary artery disease patients than depression. *European Heart Journal*, 31(13), 1573-1582. Doi: 10.1093/eurheartj/ehp602

Table 1

*Smart Heart Randomization*

Random Sequence Generator (n=30)				Random Sequence Generator (n=20)	
Intervention	Control			Intervention	Control
17	26			17	16
28	16			12	6
12	6			20	4
24	4			8	13
20	13			10	7
21	7			1	18
30	27			5	2
22	18			19	11
8	2				9
23	11				14
10	9				3
25	29				15
1	14			n=8	n=12
5	3				
19	15				

Table 2

*Outcome Evaluation Design*

<b>Outcome Evaluation</b>				
<b>Outcome</b>	<b>Measures</b>	<b>Design</b>	<b>Sources of Data</b>	<b>Data Analysis</b>
Self-care	SCHFI scores before the intervention (at discharge) and after the intervention	Pretest-posttest	SCHFI instrument collected from patient	Paired t-test
Difference in 30 day hospital readmission rates	Readmission rate for heart failure patients 30 days after discharge in control vs. experimental group (number of readmissions per 50 patient with heart failure)	Post-test only	Electronic Medical Record and telephone interview on day 31	Chi-squared analysis
Anxiety symptoms	GAD-7	Pretest-posttest	GAD-7 score collected from patient	Paired t-test
Depressive symptoms	PHQ-9	Pretest-posttest	PHQ-9 score collected from patient	Paired t-test
Difference in quality of life 1 month after discharge.	Minnesota Living with Heart Failure Questionnaire (MLHFQ) with scores are 0-105 from best to worst; scores for experimental vs. control group	Post-test only	Telephone interview Minnesota Living with Heart Failure Questionnaire (MLHFQ)	Chi-squared analysis



Table 3

*University of Kentucky HF Payer Source*

<b>Payor Source</b>	<b>FY 2014 Mix (%)</b>	<b>FY 2015 Mix (%)</b>
<b>Govt/Other</b>	<b>4.0%</b>	<b>4.1%</b>
<b>Managed Care</b>	<b>10.0%</b>	<b>10.1%</b>
<b>Medicaid</b>	<b>18.5%</b>	<b>20.9%</b>
<b>Medicare</b>	<b>64.6%</b>	<b>64.0%</b>
<b>Self-Pay/Charity</b>	<b>2.9%</b>	<b>0.9%</b>

(A. Carr, personal communication, August 3, 2015)

Table 4

*University of Kentucky Inpatient Discharges by Age*

Age Groups	FY 2014	FY 2015
Age 0-18	54	41
Age 19-44	314	374
Age 45-64	1,537	1,717
Age 65+	1,691	2,048
Grand Total	3,596	4,180

(A. Carr, personal communication, August 3, 2015)

Table 5

*Participant Demographics and Baseline Information*


	Intervention (n=8)  <i>n</i> (%)	Control (n=12)  <i>n</i> (%)	<i>p</i>
Age, <i>Mean</i> (SD)	49.5 (13.2)	48.8 (16.6)	.93
BMI, <i>Mean</i> (SD)	34.9 (15.1)	34.4 (9.9)	.93
SCHFI, pre	67.6 (12.1)	57.4 (10.2)	.06
PHQ-9, pre	6.8 (3.8)	7.5 (6.0)	.76
GAD-7, pre	2.8 (3.0)	7.0 (6.4)	.10
Gender			.55
Male	5 (62.5)	9 (75.0)	
Female	3 (37.5)	3 (25.0)	
Ethnicity			.19
Caucasian	8 (100.0)	9 (75.0)	
African-American	0 (0.0)	3 (25.0)	
Marital status			.61
Married	3 (37.5)	5 (41.7)	
Non-married	5 (62.5)	7 (58.3)	
Education			.02
Less than high school	0 (0)	3 (25.0)	
High school	5 (62.5)	9 (75.0)	
Above high school	3 (37.5)	0 (0)	
Residence			.85
Urban	5 (62.5)	7 (58.3)	

Rural	3 (37.5)	5 (41.7)	
Household income			.14
<20,000	4 (50.0)	10 (83.3)	
20,000+	4 (50.0)	2 (16.7)	
NYHA class			.04
Class I	1 (12.5)	0 (0)	
Class 2	4 (50)	2 (16.7)	
Class 3	2 (25)	5 (41.7)	
Class 4	1 (12.5)	5 (41.7)	
LVEF, <i>Mean</i> (SD)	27.1(19)	25.8 (15.1)	.86
LVEF			.34
Preserved	2 (25.0)	1(8.3)	
Non-preserved	6 (75.0)	11 (91.7)	
VAD			.14
Yes	4 (50.0)	2 (16.7)	
No	4 (50.0)	10 (83.3)	
PHQ-9			.69
Mild	6 (75.0)	8 (66.7)	
Moderate to Severe	2 (25.0)	4 (33.3)	
GAD-7			.13
Mild	8 (100.0)	9 (75.0)	
Moderate to Severe	0 (0.0)	3 (25.0)	

Table 6

*Changes in SCHFI scores, PHQ-9 scores, and GAD-7 scores Pre and Post Intervention*

Variable	Total				Intervention				Control			
	Pre		Post		Pre		Post		Pre		Post	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
SCHFI	61.1	11.2	65.2	9.2	65.7	11.7	67.6	9.6	58.2	10.3	63.6	9.0
PHQ-9	6.9	5.2	6.7	5.5	6.9	4.1	5.6	2.6	7.0	6.0	7.4	6.8
GAD-7	5.0	5.7	6.4	5.9	2.4	3.1	4.0	3.4	6.6	6.5	7.9	6.8



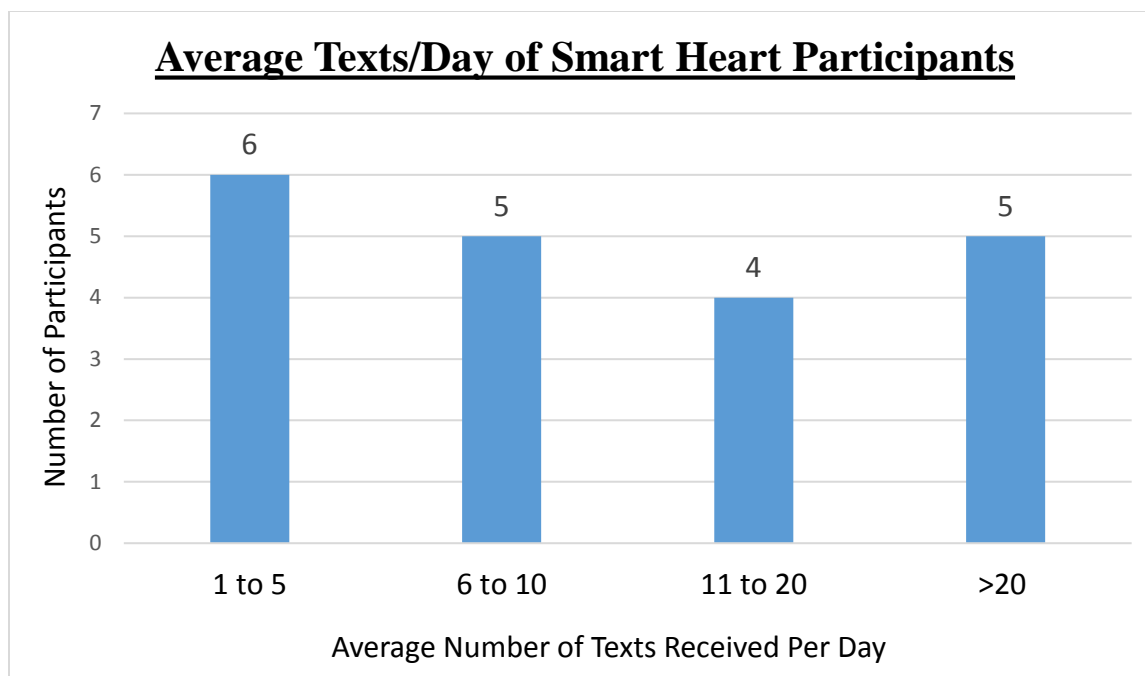
***new patient information***

name

start date

phone

*Figure 1.* Participant Test Message



*Figure 2. Average Texts Received of Smart Heart Participants*

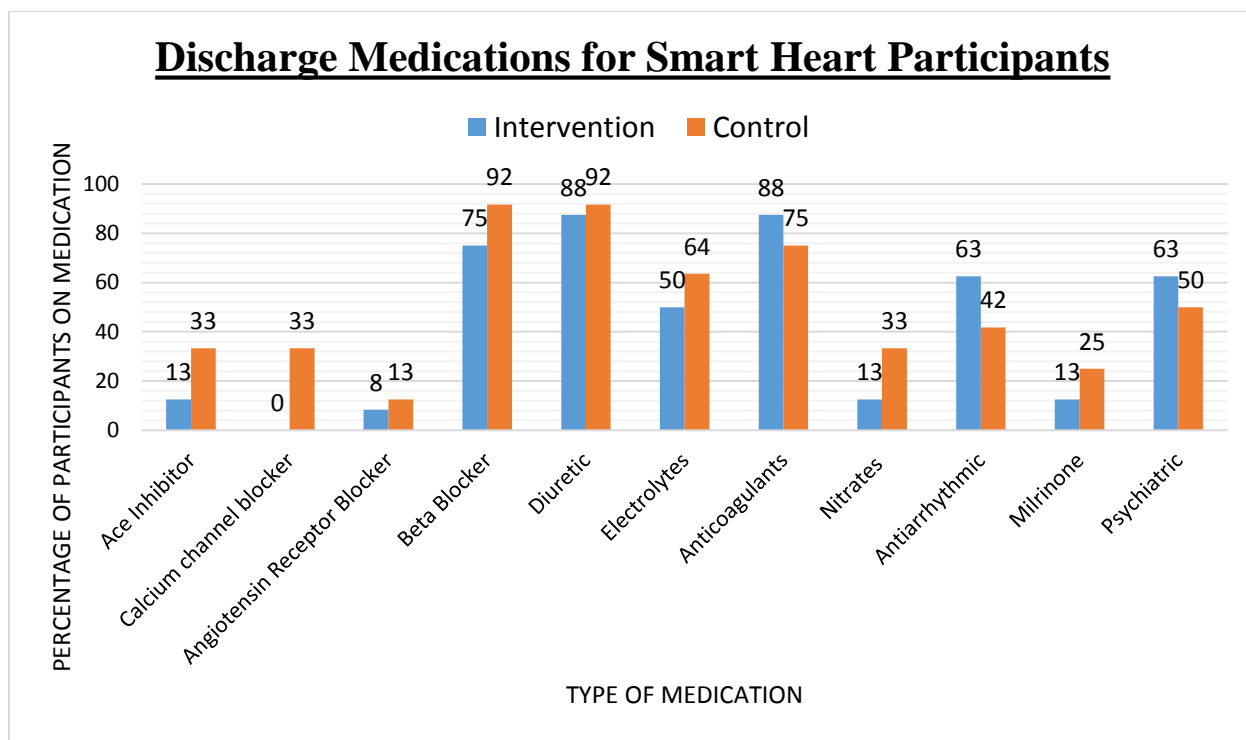
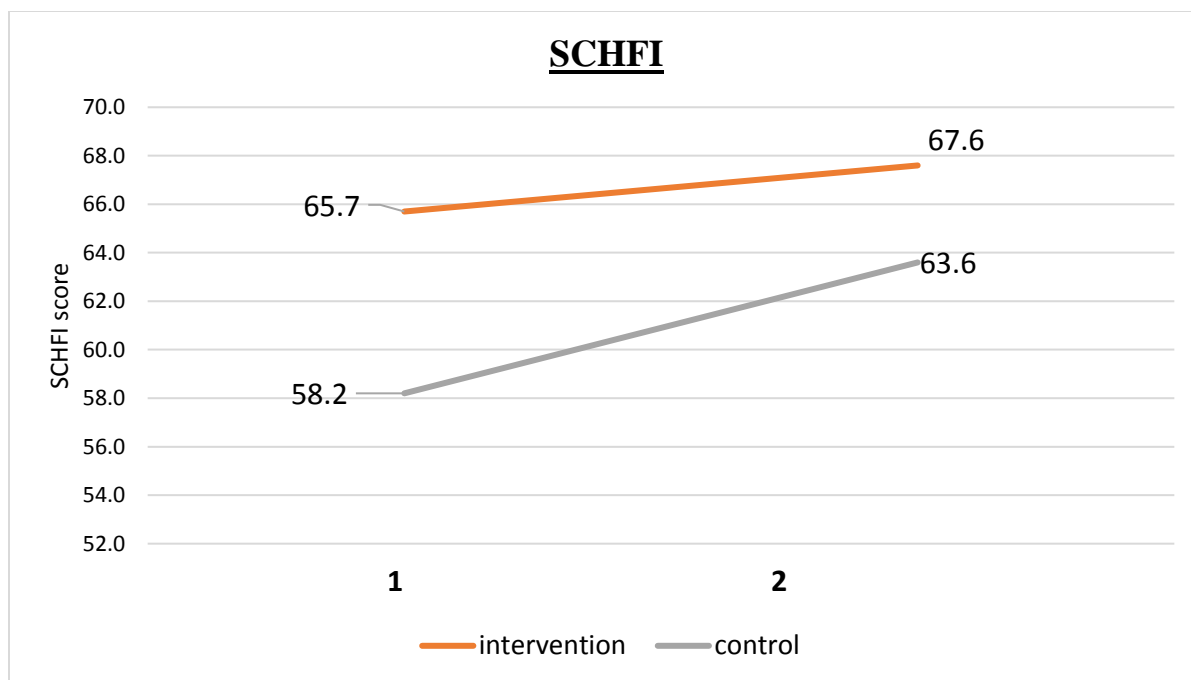


Figure 3. Discharge Medications for Smart Heart Participants

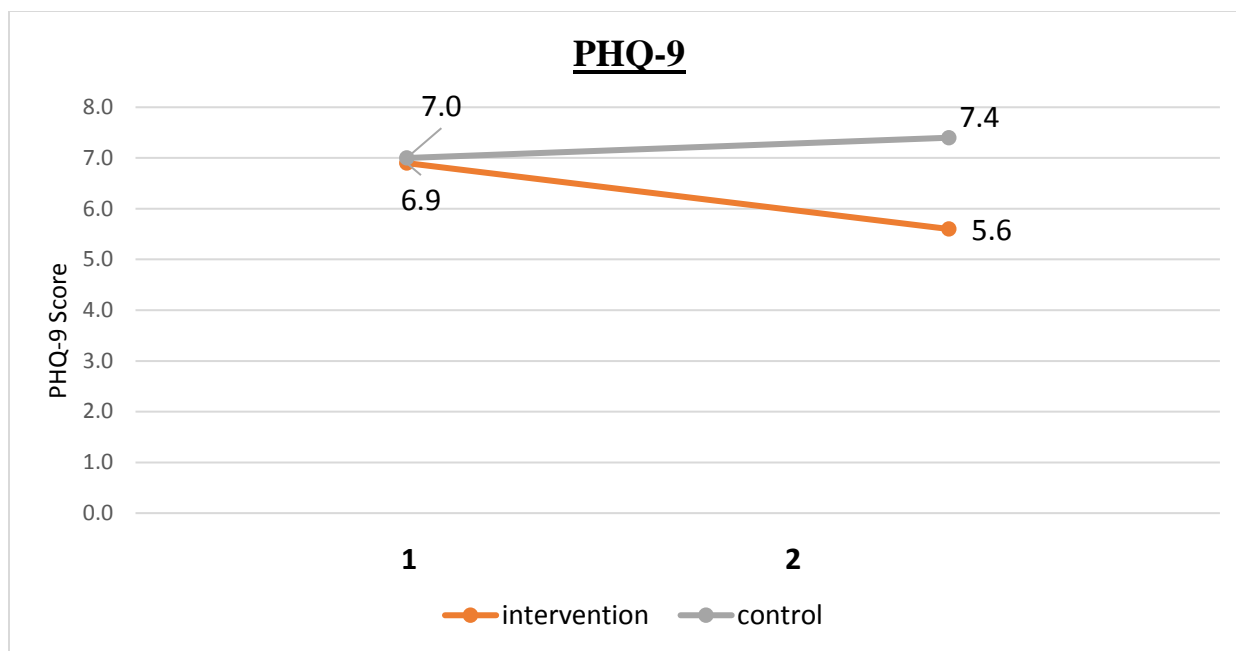




\*Note: Higher SCHFI scores= better self-care

\*1= pre-intervention and 2=post intervention

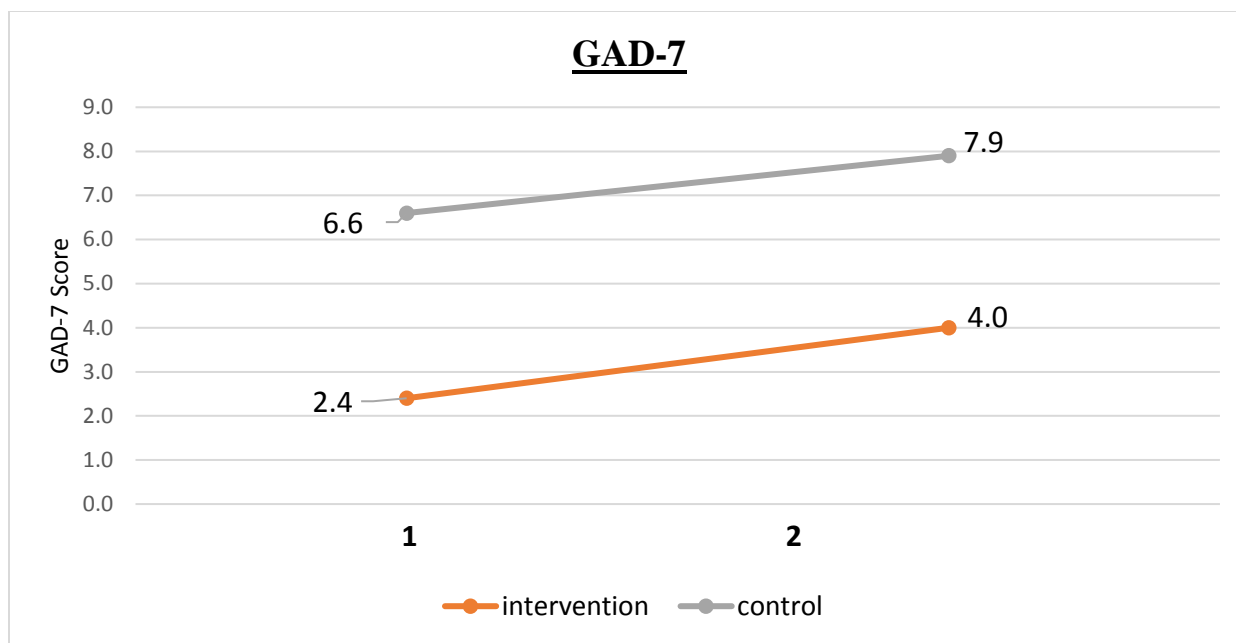
*Figure 4. SCHFI Scores Pre and Post Intervention*



\*Note: Higher PHQ-9 scores= more depression symptoms

\*1= pre-intervention and 2=post intervention

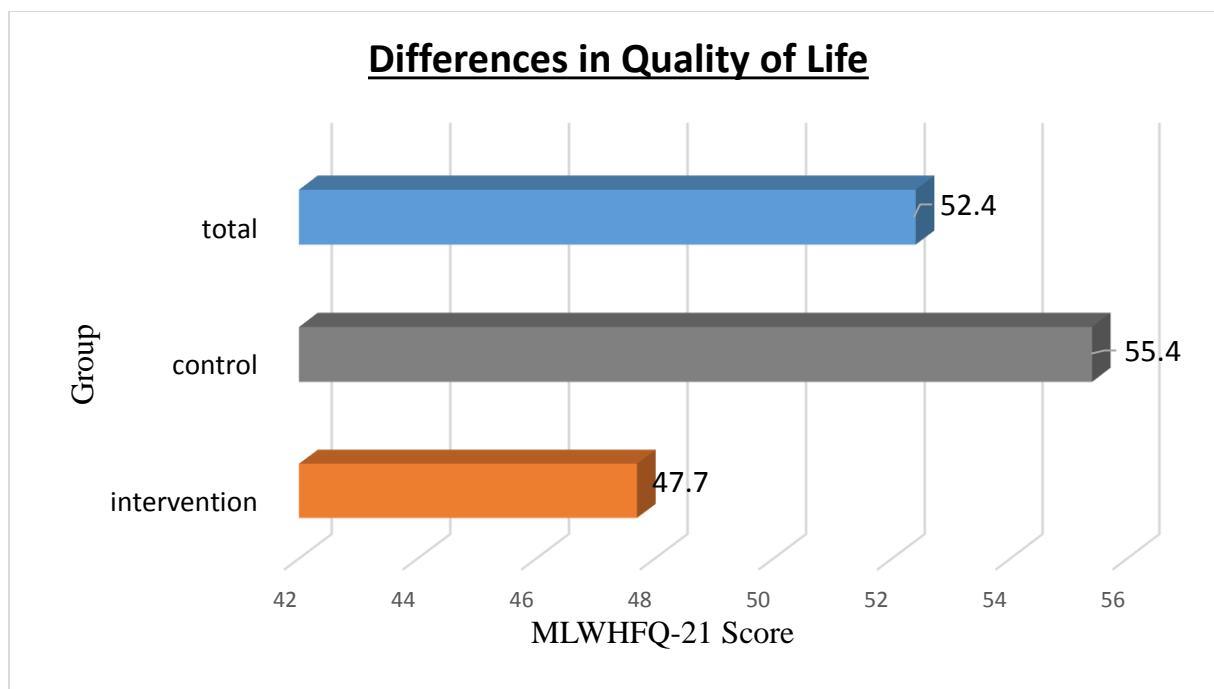
*Figure 5. PHQ-9 Scores Pre and Post Intervention*



\*Note: Higher GAD-7 scores= more anxiety symptoms

\*1= pre-intervention and 2=post intervention

*Figure 6. GAD-7 Scores Pre and Post Intervention*



\*Note: Lower scores indicate a better quality of life

*Figure 7. Differences in MLWHFQ-21 Scores Post Intervention*

Appendix A  
Self-Care of Heart Failure Index Tool

**Think about how you have been feeling in the last month or since we last spoke as you complete these items.**

**SECTION A:**

*Listed below are common instructions given to persons with heart failure. How routinely do you do the following?*

	<b>Never or rarely</b>	<i>Sometimes</i>	<i>Frequently</i>	<i>Always or daily</i>
1. Weigh yourself?	1	2	3	4
2. Check your ankles for swelling?	1	2	3	4
3. Try to avoid getting sick (e.g., flu shot, avoid ill people)?	1	2	3	4
4. Do some physical activity?	1	2	3	4
5. Keep doctor or nurse appointments?	1	2	3	4
6. Eat a low salt diet?	1	2	3	4
7. Exercise for 30 minutes?	1	2	3	4
8. Forget to take one of your medicines?	1	2	3	4
9. Ask for low salt items when eating out or visiting others?	1	2	3	4
10. Use a system (pill box, reminders) to help you remember your medicines?	1	2	3	4

**SECTION B:**

Many patients have symptoms due to their heart failure. Trouble breathing and ankle swelling are common symptoms of heart failure.

In the past month, have you had trouble breathing or ankle swelling? Circle one.

0) No

1) Yes

If you had trouble breathing or ankle swelling in the past month...

(circle **one** number)

	<b>Have not had these</b>	<b>I did not recognize it</b>	<b>Not Quickly</b>	<b>Somewhat Quickly</b>	<b>Quickly</b>	<b>Very Quickly</b>
How quickly did you recognize it as a symptom of heart failure?	N/A	0	1	2	3	4

Listed below are remedies that people with heart failure use. If you have trouble breathing or ankle swelling, how likely are you to try one of these remedies?

(circle **one** number for each remedy)

	<b>Not Likely</b>	<b>Somewhat Likely</b>	<b>Likely</b>	<b>Very Likely</b>
11. Reduce the salt in your diet	1	2	3	4
12. Reduce your fluid intake	1	2	3	4
13. Take an extra water pill	1	2	3	4
14. Call your doctor or nurse for guidance	1	2	3	4

15. Think of a remedy you tried the last time you had trouble breathing or ankle swelling.

(circle **one** number)

	<b>I did not try anything</b>	<b>Not Sure</b>	<b>Somewhat Sure</b>	<b>Sure</b>	<b>Very Sure</b>
How <u>sure</u> were you that the remedy helped or did not help?	0	1	2	3	4

### SECTION C:

In general, how confident are you that you can:

	<b>Not Confident</b>	<b>Somewhat Confident</b>	<b>Very Confident</b>	<b>Extremely Confident</b>
16. Keep yourself <u>free of heart failure symptoms</u> ?	1	2	3	4
17. <u>Follow the treatment advice</u> you have been given?	1	2	3	4
18. <u>Evaluate the importance</u> of your symptoms?	1	2	3	4
19. <u>Recognize changes</u> in your health if they occur?	1	2	3	4
20. <u>Do something</u> that will relieve your symptoms?	1	2	3	4
21. <u>Evaluate</u> how well a remedy works?	1	2	3	4

Appendix B  
Text Messaging Comfort Survey

- |  |            |           |
|--|------------|-----------|
| 1. Do you own a smart phone (circle one)   | <b>Yes</b> | <b>No</b> |
| 2. Do you have an unlimited text messaging plan? (circle one)  | <b>Yes</b> | <b>No</b> |
| 3. Are you able to receive text messages? (circle one)   | <b>Yes</b> | <b>No</b> |
| 4. Do you know how to open and view a text message? (circle one)   | <b>Yes</b> | <b>No</b> |
| 5. Do you carry your phone frequently? (circle one)  |            |           |
| <div style="display: flex; justify-content: space-around; padding: 0;"> <span><b>Always</b></span> <span><b>Sometimes</b></span> <span><b>Never/Seldom</b></span> </div> |            |           |
| 6. Have you ever used text messaging before? (circle one)  | <b>Yes</b> | <b>No</b> |
| 7.   |            |           |
| 8. Please describe how many text messages you usually receive each day (circle one)  |            |           |
| <div style="display: flex; justify-content: space-around; padding: 0;"> <span><b>1-5 messages per day</b></span> <span><b>6-10 messages per day</b></span> </div>        |            |           |
| <div style="display: flex; justify-content: space-around; padding: 0;"> <span><b>11-20 messages per day</b></span> <span><b>&gt;20 messages per day</b></span> </div>    |            |           |
| <b>11-21</b>   |            |           |

From “A Text Messaging Intervention to Improve Heart Failure Self-Management After Hospital Discharge in a Largely African-American Population: Before-After Study,” by S. Nundy, R. Razi, J. Dick, B. Smith, A. Mayo, A. O’Connor, and D. Meltzer, 2013, *Journal of Medical Internet Research*, 15, p. e53. Copyright [2013] by S. Nundy, R. Razi, J. Dick, B. Smith, A. Mayo, A. O’Connor, and D. Meltzer. Reprinted [or Adapted] with permission from copyright: This is an open-access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/2.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work, first published in the Journal of Medical Internet Research, is properly cited.

Appendix C  
Patient Health Questionnaire-9 (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE - 9				
Over the <u>last 2 weeks</u> , how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3
<div style="text-align: right; margin-bottom: 5px;"><i>FOR OFFICE CODING</i></div> <div style="text-align: right;"> <u>0</u> + <u>      </u> + <u>      </u> + <u>      </u>            =Total Score: <u>      </u> </div>				
<p>If you checked off <u>any</u> problems, how <u>difficult</u> have these problems made it for you to do your work, take care of things at home, or get along with other people?</p> <div style="display: flex; justify-content: space-around; margin-top: 10px;"> <div style="text-align: center;"> <b>Not difficult at all</b>  <input type="checkbox"/> </div> <div style="text-align: center;"> <b>Somewhat difficult</b>  <input type="checkbox"/> </div> <div style="text-align: center;"> <b>Very difficult</b>  <input type="checkbox"/> </div> <div style="text-align: center;"> <b>Extremely difficult</b>  <input type="checkbox"/> </div> </div>				
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Appendix D  
Generalized Anxiety Disorder-7 Scale (GAD-7)

GAD-7

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all	Several days	More than half the days	Nearly every day
1. Feeling nervous, anxious or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it is hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3

Total Score — = Add Columns — + — + —

If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?

Not difficult  
at all

☐

Somewhat  
difficult

☐

Very  
difficult

☐

Extremely  
difficult

☐

Appendix E  
Minnesota Living with Heart Failure Questionnaire-21 (MLWHFQ-21)

**MINNESOTA LIVING WITH HEART FAILURE® QUESTIONNAIRE**

The following questions ask how much your heart failure (heart condition) affected your life during the past month (4 weeks). After each question, circle the 0, 1, 2, 3, 4 or 5 to show how much your life was affected. If a question does not apply to you, circle the 0 after that question.

<b>Did your heart failure prevent you from living as you wanted during the past month (4 weeks) by -</b>	<b>No</b>	<b>Very Little</b>				<b>Very Much</b>
1. causing swelling in your ankles or legs?	0	1	2	3	4	5
2. making you sit or lie down to rest during the day?	0	1	2	3	4	5
3. making your walking about or climbing stairs difficult?	0	1	2	3	4	5
4. making your working around the house or yard difficult?	0	1	2	3	4	5
5. making your going places away from home difficult?	0	1	2	3	4	5
6. making your sleeping well at night difficult?	0	1	2	3	4	5
7. making your relating to or doing things with your friends or family difficult?	0	1	2	3	4	5
8. making your working to earn a living difficult?	0	1	2	3	4	5
9. making your recreational pastimes, sports or hobbies difficult?	0	1	2	3	4	5
10. making your sexual activities difficult?	0	1	2	3	4	5
11. making you eat less of the foods you like?	0	1	2	3	4	5
12. making you short of breath?	0	1	2	3	4	5
13. making you tired, fatigued, or low on energy?	0	1	2	3	4	5
14. making you stay in a hospital?	0	1	2	3	4	5
15. costing you money for medical care?	0	1	2	3	4	5
16. giving you side effects from treatments?	0	1	2	3	4	5
17. making you feel you are a burden to your family or friends?	0	1	2	3	4	5
18. making you feel a loss of self-control in your life?	0	1	2	3	4	5
19. making you worry?	0	1	2	3	4	5
20. making it difficult for you to concentrate or remember things?	0	1	2	3	4	5
21. making you feel depressed?	0	1	2	3	4	5

Appendix F  
Patient Satisfaction Survey

- 1. Did you find the Self Care Heart Failure Index Tool (SCHFI) you completed before discharge easy to use?      Yes    No**

**a. If no, why?**

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- 2. Did you receive a hard copy of the self-care education before discharge?**  
**Yes    No**

- 3. Did you feel overwhelmed by the education you received before discharge?**  
**Yes    No**

**a. If yes, please describe:**

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- 4. Is there any time of day you would like to receive the daily self-care telephone messages?    Yes    No**

**a. if yes, please circle a time you prefer below.**

8:00am-12:00 pm      12:00pm-4:00 pm      4:00pm-7:00 pm      after 7 pm

- 5. Do you find the telephone based self-care messages helpful?    Yes    No**

- 6. Was it easy to take the post Self Care Heart Failure Index Tool (SCHFI) over the phone with the nurse?      Yes    No**

**a. If no, please explain**

why \_\_\_\_\_

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- 7. Are you with the Self-Care First Heart Failure Program?      Yes    No**

- 8. What parts of the program did you like?**

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**9. What parts of the program did you dislike?**

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**10. What parts of the program would you change?**

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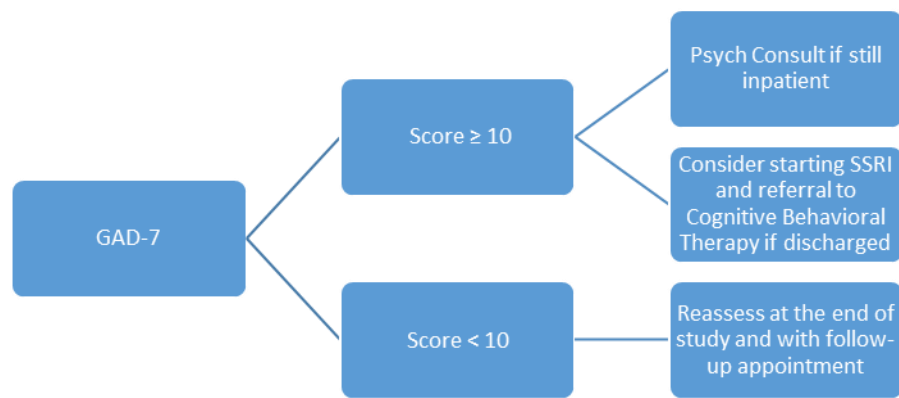
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**Thank you for participating in the Smart Heart Self-Care First Pilot Program! We appreciate your support! Please let us know if there is anything we can do to make your experience better.**

## Appendix G Depression and Anxiety Screening Protocol

### Part I: Anxiety (GAD-7 Scale)

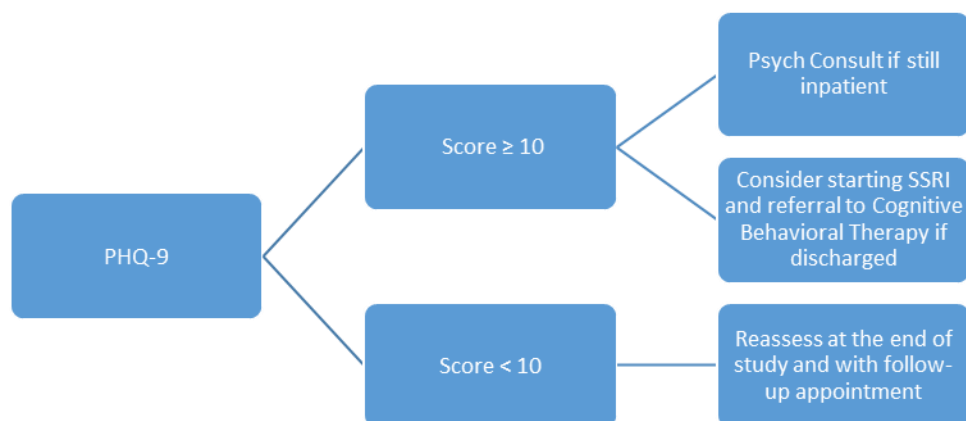
- 5: mild anxiety
- 10: moderate anxiety
- 15: severe anxiety
- $\geq 10$ : probably diagnosis of GAD; must be further evaluated by Psychiatrist for official diagnosis (Psych Consult)
- Consider starting SSRI; 1<sup>st</sup> line treatment for anxiety
- May refer to Behavioral Therapy if already outpatient and patient expresses interest



\*Note: Patients who score  $>$  or equal to 10 will be reassessed 30 days after discharge for anxiety symptoms.

### Part II: Depression (PHQ-9)

- 0-4: none
- 5-9: mild depressive symptoms
- 10-14: moderate depressive symptoms
- 15-19: moderately severe depressive symptoms
- 20-27: severe depressive symptoms
- $\geq 10$ : high specificity and sensitivity for major depressive disorder; must be further evaluate by Psychiatrist for diagnosis (Psych Consult)
- Consider starting SSRI, SNRI, Buspirone, or other anti-depressants based on patient needs determined by provider



\*Note: Patients who score  $\geq$  or equal to 10 will be reassessed 30 days after discharge for depression symptoms.

Appendix H  
Smart Heart Participant Recruitment Flyer

**UNIVERSITY OF KENTUCKY RESEARCH**

  
**SMART HEART**  
"get text & get pumped"

Researchers at the University of Kentucky are inviting adults with heart failure of any stage to participate in a research study. Participants must be able to receive text messaging and have experience with opening texts.

**Enroll today and receive:**

- Daily text messages for thirty days after discharge with suggestions on how to care for yourself
- A free pill organizer
- A calendar to track your daily weights

**You may be eligible to participate if you:**

- Are 18 years of age or older;
- Have a left ventricular assist device (LVAD);
- Have been hospitalized for heart failure; and
- Are going to be discharged from the University of Kentucky.

**WANT TO JOIN?**

**Ask these members of your care team:**

- Nurse Practitioner: Candice Falls, APRN
- Discharge Planner: Krista Lewis, RN

Thank you for your interest in the Smart Heart self care program. We look forward to working with you and helping you learn more about your heart failure so you can be a healthier you!

**Contact Information:**  
Samantha Mancuso  
sam.mancuso@uky.edu  
(270) 792-8157

  
*An Equal Opportunity University*

**www.UKclinicalresearch.com**

Appendix I  
Demographic Information Sheet

**Smart Heart 4 digit ID #:** \_\_\_\_\_

**Age:** \_\_\_\_\_

**County of Residence:** \_\_\_\_\_

**Family Contact and Phone Number** \_\_\_\_\_

**Gender (circle one)**                      **Male**                      **Female**

**Marital Status (circle one)**

Single                      Married                      Widowed                      Divorced

**Number of Persons in Household:** \_\_\_\_\_

**Race (circle one):**

Caucasian/White                      African American                      Latino/Hispanic                      Asian American  
Pacific Islander

**Highest Education level completed (circle one):**

Less than high school                      High school education/GED                      College degree  
Graduate level degree

**Median Household Income (circle one):**

< \$20,000/yr                      \$21,000-40,000/yr                      \$41,000-60,000                      \$61,000-80,000/yr  
\$81,000-100,000/yr                      > \$100,000/yr

**NYHA Class:**

\_\_\_\_\_ **(I)** No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath)

\_\_\_\_\_ **(II)** Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath)

\_\_\_\_\_ **(III)** Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea

\_\_\_\_\_ **(IV)** Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases



To be completed by PI through review of medical records and interview:

**Left ventricular Ejection Fraction (EF):** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Review of Current Medications:**

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**Number of Readmissions in the last year at UK and other hospitals:** \_\_\_\_\_

**Height:** \_\_\_\_\_

**Weight:** \_\_\_\_\_

**BMI:** \_\_\_\_\_

**LVAD? (yes or no):** \_\_\_\_\_

**Objective NYHA Class (A, B, C, or D):** \_\_\_\_\_

### Appendix J Text Messaging Plan

DIET/ FLUIDS	MEDS	WEIGHT	SIGNS OF FLARE UP	MEDS	WEIGHT	EXERCISE/ COPING
Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Welcome to the Self-Care First Heart Failure Program! We are glad you have agreed to join our study. Heart failure means that your heart can't pump as good as it used to. This causes low blood flow to other parts of the body and a weak heart. Self-care is the best way to manage your disease. Our goal is to increase your confidence so you can lead a healthy life!	Take your medications as directed by your provider. Take each medicine at the same time of day and let your provider know of any side effects. If you miss a dose, take it as soon as you remember unless it is time for your next dose. Do not change the dose of the medicine or stop taking the medicine unless your provider tells you to.	Weighing yourself daily can help alert you to extra fluid in the body. Weigh yourself the same time each morning, with the same amount of clothes, before you eat, and after urinating to get an accurate measure. Keep track of your weight on a calendar and call your provider if you gain more than 2 pounds in 1 day.	If you notice swelling of the ankles or lower legs, you may have too much fluid in the body. Tightly fitting shoes or clothes may also be a sign of a flare-up or worsening heart failure. Let your provider know if you have these signs.	Drugs that end in -olol are called beta blockers. Examples are carvedilol or metoprolol. They can lower blood pressure and slow down heart rate. These drugs can make you feel tired at first but over time help the heart pump better and prevent further damage!	Make sure you are getting your daily weight in! Reach out to your provider if you are unable to get a scale for some reason. Sudden weight gain of more than 2 pounds in 1 day or more than 5 pounds in a week means you should call your provider!	Some people may have follow-up visits after being hospitalized as soon as 7 days after discharge. Bring your calendar with your daily weights to your appointment and write down any questions you may have for your provider. Your provider may have you bring your medications as well.
Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14

Too much salt in the diet can cause your body to keep excess fluid. The daily goal of salt in the diet is less than 3 grams. Some foods high in salt are canned, dried, packaged, frozen, or fast foods. Try using salt substitutes to reduce your intake!	Drug that end in -pril lower blood pressure and decrease the work of the heart. They are important for increasing strength of the heart. If you notice that you develop a cough with this medicine, contact your provider.	Gaining weight suddenly or a steady rise in weight is the first warning sign of worsening heart failure. Remember to weigh yourself every day and keep track of your weight on a calendar or in a journal. If you gain more than 2 pounds in 1 day or more than 5 pounds in 1 week, call your provider.	Your heart failure may be getting worse if you have trouble breathing with activity or at rest, if you wake up in the middle of the night short of breath, coughing, or need to use more pillows than normal to sit/sleep. Call your provider if you have these symptoms.	Water pills help the body to get rid of excess fluid. These are drugs like furosemide, metolazone, or spironolactone. They can decrease swelling and make it easier for the heart to pump. Sometimes water pills cause low potassium levels. Your provider may have prescribed you potassium to take with your water pill.	Daily weights can help keep you out of the hospital. Remember you are looking for a 2-pound weight gain in one day or a 5 pound weight gain in 1 week. If you notice this trend, contact your provider immediately. They may have you take an extra water pill.	Exercise in the form of simple activities such as walking is encouraged most days of the week. Rest as you need it and stop activity if you have chest pain, have trouble breathing, feel dizzy or lightheaded.
<b>Day 15</b>	<b>Day 16</b>	<b>Day 17</b>	<b>Day 18</b>	<b>Day 19</b>	<b>Day 20</b>	<b>Day 21</b>
Drinking too much fluid can lead to a flare-up. Keep track of what you are drinking and limit alcohol. Men should have less than 2 drinks/day and women less than 1 drink/day of alcohol. Try frozen fruits to quench your thirst or popsicles!	Digoxin helps the heart pump stronger. It increases the amount of blood that your heart can pump with each beat. It lowers your heart rate and sometimes requires blood monitoring. Signs of toxicity include drowsiness, headache, confusion, vision changes, and GI symptoms.	When you see your doctor at regular clinic appointments, don't forget to bring your recorded weights! Your doctor may need to adjust your water pill dose based on this information. If you gain more than 2 pounds in 1 day or more than 5 pounds in 1 week, tell your provider.	Warning signs of a flare- up include feeling weak, dizzy, or more tired than usual. You may have chest pain or a cough that won't go away with increasing shortness of breath. You may have trouble remembering things or don't feel hungry. Be sure to let your provider know if you are feeling this way.	Hydralazine and drugs with "nitro" in them work together to treat heart failure. They lower blood pressure and make it easier for the heart to pump. Rise from a sitting to standing position slowly because these medications may decrease your blood pressure fast.	Use the same scale every day at the same time with the same amount of clothes on. Put the scale on a flat surface. If you miss a day of weighing yourself, just weigh yourself the next morning! Don't forget to call your provider if you gain more than 2 pounds in 1 day or more than 5 pounds in 1 week.	Depression can be common among people with heart failure. If you feel helpless, worthless, or that life is not worth living, be sure to share these feelings with your provider so they can help you. Seeking treatment for these feelings can help improve your overall health.
<b>Day 22</b>	<b>Day 23</b>	<b>Day 24</b>	<b>Day 25</b>	<b>Day 26</b>	<b>Day 27</b>	<b>Day 28</b>

Low salt foods that are healthy include yogurt, fruit, fresh or frozen vegetables, whole oats, olive oil, vinegar, fresh meats, dried beans, unsalted margarine, graham crackers, lemon slices, frozen fruit, eggs, and fresh fish.	Using a pill box or a reminder system can be useful when managing your medications. You can fill the pillbox at the start of each week so you don't forget which medications to take every day.	Hopefully you have an entire month filled in on your calendar with daily weights! Record your weight for each day on a calendar is the easiest way to keep track of weight gain. If you gain more than 2 pounds in 1 day or more than 5 pounds in 1 week, call your provider.	For emergencies such as severe shortness of breath where you can't catch your breath, severe chest pain that is not relieved by nitroglycerin or rest, pink, foamy mucus with cough, continuous rapid or irregular heartbeat, passing out, fainting, or stroke like symptoms such as numbness of weakness on one side of your body (face, arm, and legs) call 911.	Have a family member or friend help you with your medications. It is the best way to include them in your care and it gives you something to do together! They can help you with your pill calendar or take you to the pharmacy to refill prescriptions.	Recording your weight before breakfast and after emptying your bladder with the same kind of clothes on can help you know when you might have a flare up. Remember you are looking for a 2 pound weight gain in 1 day or 5 pounds over 1 week. Call your provider if you see this pattern!	Get up and get dressed every day with a plan to do an activity you enjoy! For exercise safety 1) rest when you feel short of breath 2) wear good socks and shoes 3) start slow and 4) don't push yourself on days you don't feel well.
<b>Day 29</b>	<b>Day 30</b>					
Fresh fruits and vegetables help keep your heart healthy. Pair them with fish, chicken, and other meats. Be sure not to add salt to your food! You can use substitutes such as pepper and seasonings from	Remember to talk to your doctor about medication side effects and cost. If you are having trouble getting your medicine or have questions, be sure to contact your provider!					

Bornstein et al. (2011)